

# TRUTH IN TRANSPARENCY DURABILITY

## Long-term Outcomes of Mosaic versus Perimount Mitral Replacements: 17-year Follow-up of 940 Implants

Tyler J. Beute, M.D., RN | Matthew Goehler, B.Sc.  
Jessica Parker, M.S., Gstat | Theodore Boeve, M.D.  
John Heiser, M.D. | Edward Murphy, M.D.  
Tomasz Timek, M.D., Ph.D. | Charles L. Willekes, M.D.

### Study Objective

Compare the long-term outcomes of Mosaic™ porcine mitral valves to Carpentier-Edwards bovine pericardial mitral valves.

### Study Findings

In long-term follow-up of patients younger than 65 years of age undergoing mitral valve replacement, **Perimount Magna™ valves experienced significantly earlier and more frequent structural valve deterioration than Mosaic.**

Survival at 15 years was 24.0% for porcine and 15.5% for bovine implants, which was not significantly different.

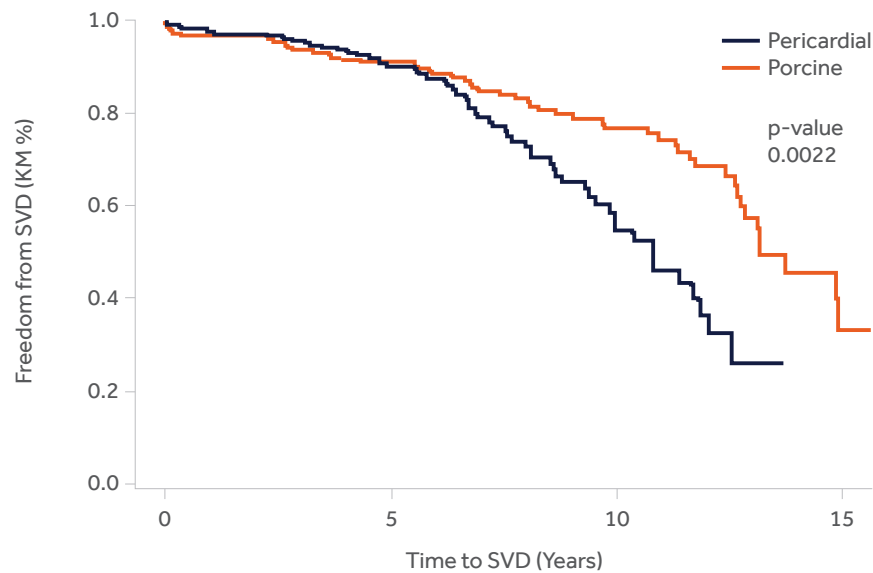
### Study Details

- 463 Mosaic mitral porcine bioprostheses, 477 Magna mitral pericardial bioprostheses
- Significant # of patients < 65 (average age 68.6 yrs ± 12)
- 99% completed follow-up (mean follow-up 6.6 years)
- Propensity-matched
- Used echo to determine SVD (all explants went to pathology)

**Note:** This study was larger than the mitral IFU studies for Mosaic, Perimount, Epic, or Biocor.

## Study Results

### SVD\* Curve Diverges at 5 Years



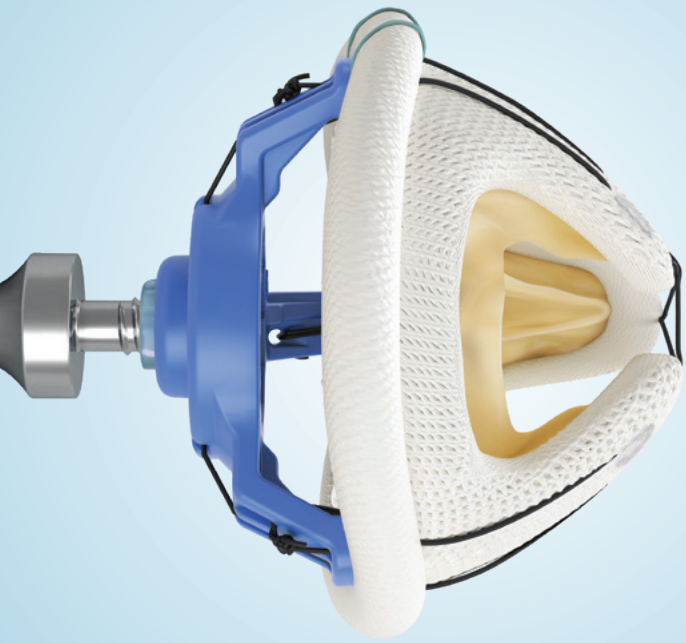
### Cumulative Incidence of Reoperation for SVD

"The rate of overall reoperation for pericardial valves is 1.89 times higher than that for porcine valves."<sup>1</sup>

### Incidence of reoperation due to SVD at 15 years

- 13.2% for Perimount Magna pericardial
- 7.9% for Mosaic porcine

\*Freedom from echocardiographic structural valve deterioration.



**Mosaic™**  
Bioprosthesis

## A High Standard of Durability

Peer-reviewed, published articles demonstrate Mosaic durability out to 15 years.

Published	Average age	Freedom from explant for SVD/# of patients at risk	
		10 years	15 years
Beute <sup>1</sup>	68.6 ± 12	97%/116	90.5%/18
Riess <sup>2</sup>	67.9 ± 10	94.4%/93	79.7%/15
Celiento <sup>3</sup>	73 ± 10	93%/23	93%/4

**References**

- <sup>1</sup> Beute TJ, Goehler M, Parker J, et al. Long-Term Outcomes of Mosaic Versus Perimount Mitral Replacements: 17-Year Follow-Up of 940 Implants. *Ann Thorac Surg*. Published online December 20, 2019.
- <sup>2</sup> Riess FC, Fradet G, Lavoie A, Legget M. Long-term outcomes of the Mosaic bioprosthesis. *Ann Thorac Surg*. March 2018;105(3):763-769.
- <sup>3</sup> Celiento M, Blasi S, De Martino A, Pratali S, Milano AA, Bortolotti U. The Mosaic mitral valve bioprosthesis: a long-term clinical and hemodynamic follow-up. *Tex Heart Inst J*. February 1, 2016;43(1):13-19.

**Mosaic™ Bioprosthesis**

**Indications:** For the replacement of malfunctioning native or prosthetic aortic and/or mitral heart valves.

**Contraindications:** None known.

**Warnings/Precautions/Adverse Events:** Accelerated deterioration due to calcific degeneration of bioprosthesis may occur in: children, adolescents, young adults, and patients with altered calcium metabolism (e.g., chronic renal failure, hyperparathyroidism). Adverse events can include: angina, cardiac arrhythmia, cardiac dysrhythmias, death, endocarditis, infection other than endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction, stroke, structural deterioration, thromboembolism, or valve thrombosis.

**Caution:** Federal law (USA) restricts these devices to sale by or on the order of a physician.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use. For countries that use eIFUs, consult instructions for use at this website: [www.medtronic.com/manuals](http://www.medtronic.com/manuals). Note: Manuals can be viewed using a current version of any major internet browser.

**medtronic.ca**

Medtronic Canada  
99 Hereford Street  
Brampton, Ontario L6Y 0R3  
Tel: (800) 268-5346