Medtronic

Mosaic™ mitral bioprosthesis

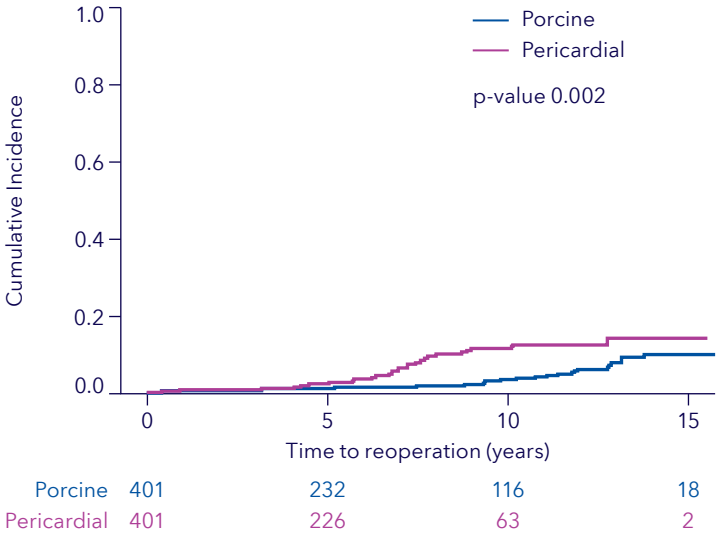
Unsurpassed durability

Mosaic mitral has demonstrated industry-leading durability.

Data has shown better durability with Mosaic porcine compared to Edwards pericardial, while other studies have shown better durability with Edwards pericardial compared to Epic porcine, indicating that porcine tissue durability may not be a class effect.

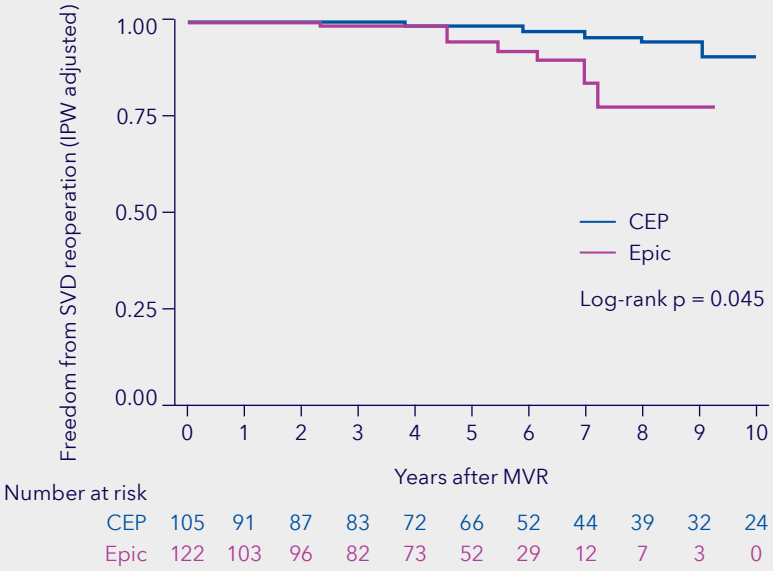
Beute[8]

- Propensity score matched analysis of 802 patients implanted with either a Mosaic porcine bioprosthesis or a Carpentier-Edwards™* pericardial bioprosethesis
- Cumulative incidence of all-cause reoperation and reoperation for SVD specifically were significantly lower for Mosaic mitral valve as compared to the Edwards pericardial valve
- **Rate of reoperation for pericardial valves was 1.89 times higher than that for Mosaic porcine valves**
- **Rate of reoperation for SVD for pericardial valves was 2.32 times higher than that for Mosaic porcine valves**



Uchino†,11

- Inverse probability of treatment adjusted analysis comparing the Epic porcine bioprosthesis to the Carpentier-Edwards pericardial bioprosthesis
- **Rates of freedom from reoperation for SVD were significantly lower for Epic as compared to the pericardial valve**



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† All-cause rate of reoperation was not reported.

Quality of data matters.

Mosaic is one of the most well-studied mitral tissue valves in terms of long-term follow-up. The platform is built upon more than 50 years of clinical experience.

Paper	Valve studied	Study design	MVR arm N =	Avg. age	Avg. years of f/up	**Reporting time point**
Tomsic[1] Clinical outcomes following mitral valve replacement with Epic and Mosaic bioprosthetic valves	Epic mitral	retrospective, single-center	247	72.9	2.95	**10 years**
Jawad[2] Midterm results after St. Jude Medical Epic porcine xenograft for aortic, mitral, and double valve replacement	Epic mitral	Prospectively acquired hospital database results	892	71.2	3.04†	**10 years**
Anselmi[3] Durability of mitral valve replacement with a third generation bioprosthesis	Epic mitral	Single-center	482	68.1	3.8	**10 years**
Lehmann[4] Porcine xenograft for aortic, mitral, and double valve replacement: long-term results of 2544 consecutive patients	Epic mitral	Prospective review of hospital-acquired database	347	73.8	4.5†	**10 years**
Tomsic[1] Clinical outcomes following mitral valve replacement with Epic and Mosaic bioprosthetic valves	Mosaic mitral	retrospective, single-center	88	70.9	3.48	**10 years**
Chiariello[5] Late results after mitral valve replacement with Mosaic bioprosthesis in patients aged 65 years or younger	Mosaic mitral	Review of stored medical records	67	58.5	4.7	**10 years**
Lorusso[6] Mitral Valve Replacement With a Third-Generation Porcine Valve: An Italian Multicentered Study	Mosaic mitral	Retrospective, multi-center	805	73.5	3.7‡	**10 years**
Yoshikawa[7] Long-term Outcomes of the Mosaic Mitral Porcine Bioprosthesis in Japan	Mosaic mitral	Retrospective, multi-center	390	73§	4.83◊	**12 years**
Beute[8] Long-Term Outcomes of Mosaic versus Perimount Mitral Replacements:17-Year Follow-Up of 940 Implants	Mosaic mitral	Retrospective, single-center, propensity matched	477	68.5	7.0	**15 years**
Celiento[9] The Mosaic Mitral Valve Bioprosthesis: A Long-Term Clinical and Hemodynamic Follow-Up	Mosaic mitral	Retrospective, single-center	100	73	6	**15 years**
Reiss[10] Long-term Outcomes of the Mosaic Bioprosthesis	Mosaic mitral	Prospective, multi-center, non-randomized	232	67.9	8.5	**16 years**

† Follow-up for MVR patients not given; this value is the average for the entire study cohort.
‡ Median follow-up was 44 months (IQR 16-63 months).
§ Median (interquartile range [IQR]) age of the cohort was 73 (69-77 years).
◊ Median (IQR) follow-up was 4.83 (1.84-8.26) years.
The table above is current as of February 2024. Only published, peer-reviewed papers with reporting results at 10 years or more were included.

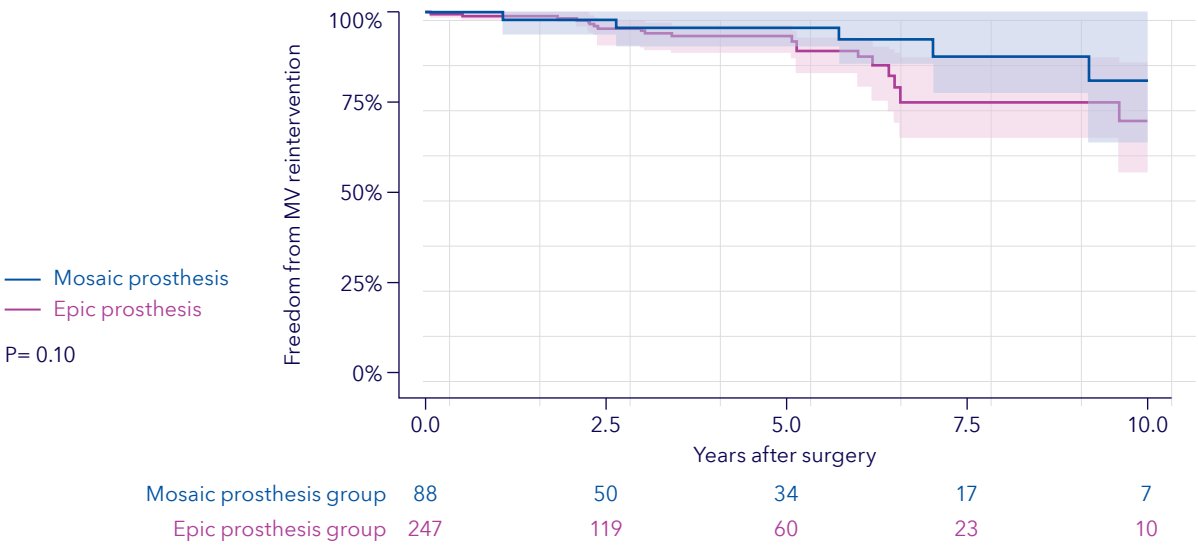
Clinical outcomes after mitral valve replacement with Epic™* and Mosaic bioprosthetic valves.[1]

A retrospective, single-center study from Leipzig Heart Center in Germany analyzed long-term outcomes for 335 patients undergoing isolated mitral valve replacement (247 Epic, 88 Mosaic). Maximum follow up was 10 years, median follow up was 3.00 years (2.95 for the Epic group and 3.48 for the Mosaic group), looking at mitral valve reintervention as primary endpoint:

- 26 total reinterventions during follow up
  - 20 in Epic group (8.1% of 247 patients)
  - 6 in Mosaic group (6.8% of 88 patients)
- Causes of reintervention were:
  - Endocarditis = 10 (8 Epic, 2 Mosaic)
  - Valve thrombosis = 5 (4 Epic, 1 Mosaic)
  - SVD = 5 (3 Epic, 2 Mosaic)
  - Paravalvular leak = 2 (1 Epic, 1 Mosaic)
  - Unknown = 7 (all Epic)

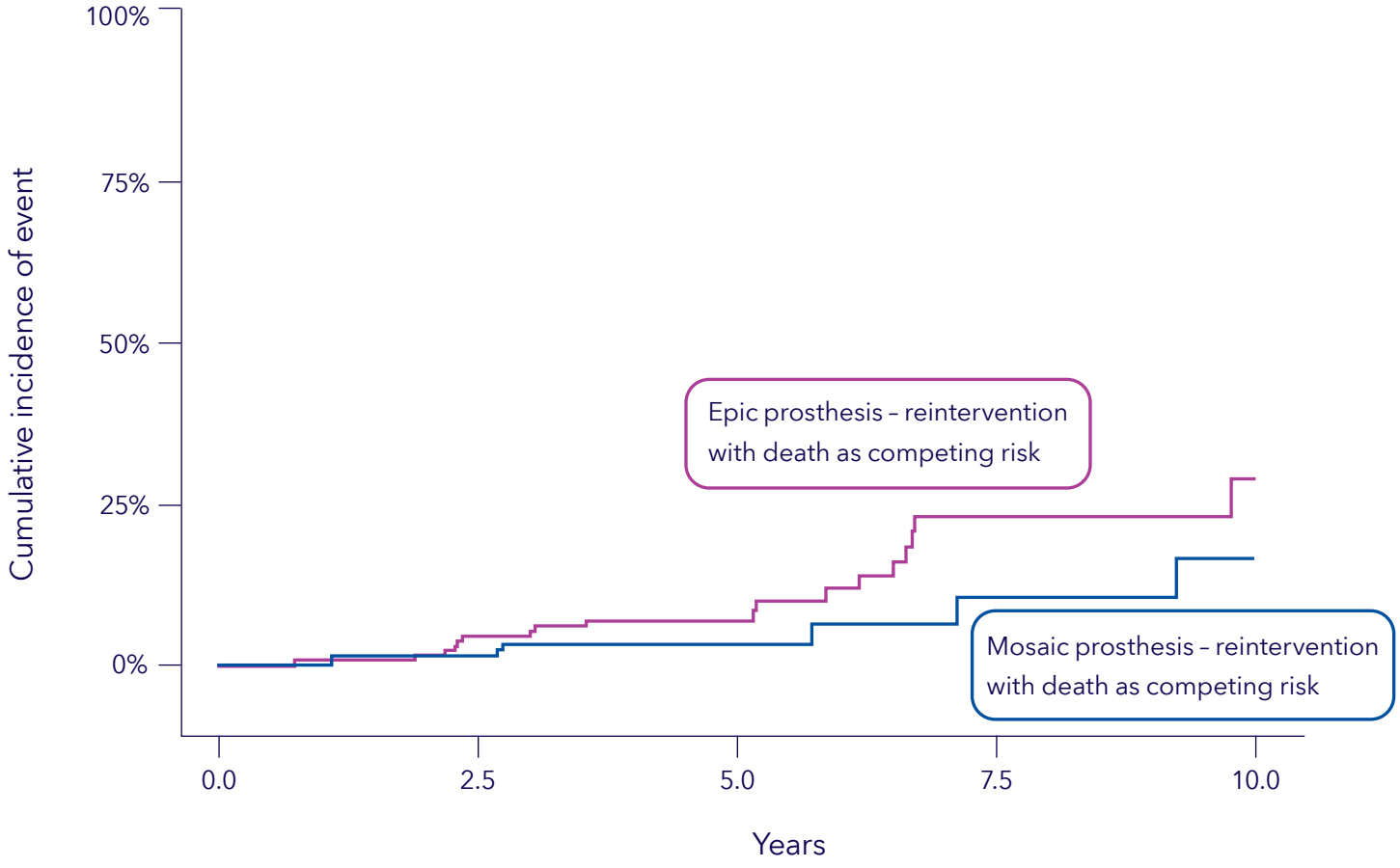
- The 10-year freedom from definite (confirmed on reoperation) SVD was 89.4% in the Epic group and 91.7% in the Mosaic group. However, there were seven reinterventions in the Epic group with unknown cause.
- At 10 years, the estimated **freedom from reintervention rates were 62.2% (95% CI, 42.8%–84.5%) and 79.1% (95%, CI 62.1%–100%) for the Epic and Mosaic groups,** respectively, with no statistically significant differences between groups (P = .10), but an evident trend was observed.

Kaplan-Meier estimated freedom from mitral valve reintervention rates



Clinical outcomes after mitral valve replacement with Epic and Mosaic bioprosthetic valves.[1] (cont'd.)

At 10 years postoperative, the cumulative incidence functions of reintervention with death as competing risk were **34.4%** for the Epic group and **17.6%** for the Mosaic group. Multivariate analysis for mitral valve reintervention found the type of mitral valve prosthesis just failed to reach statistical significance, but was favoring Mosaic (Hazard ratio, 0.43 for Mosaic valve; P = .067)†



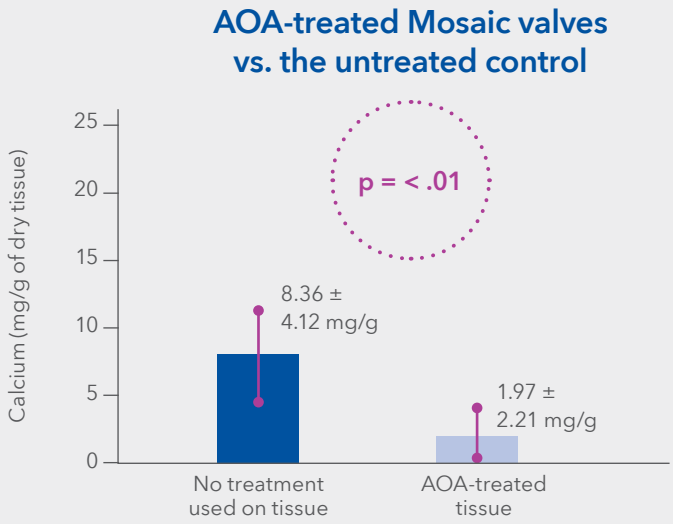
"At 10 years after MVR, the cumulative incidence of reintervention was twice as high in the Epic group."

†95% CI 32.7% - 36.1% in the Epic group; 16.2% - 18.9% in the Mosaic group.

Built for a life. Time tested.

Designed to enhance durable valve replacement and patient lifetime management, the Medtronic innovative AOA™ tissue treatment is used across a suite of Medtronic devices, including Mosaic valves. Clinical use with these devices encompasses more than half a million patients for over 30 years.†

The Medtronic AOA treatment demonstrated a significant reduction in calcium versus untreated controls in an animal study.[12]



† The benefits of AOA tissue treatment have been demonstrated through animal testing. No direct clinical evaluation of the benefits of AOA treatment in humans has been conducted.

1. Tomsic A, Marin-Cuartas M, De La Cuesta M, et al. Clinical Outcomes After Mitral Valve Replacement With Epic and Mosaic Bioprosthetic Valves. *Ann Thorac Surg Short Reports*. June 2024;2(2):P251–256.
2. Jawad K, Lehmann S, Koziarz A, et al. Midterm results after St Jude Medical Epic porcine xenograft for aortic, mitral, and double valve replacement. *J Card Surg*. August 2020;35(8):1769-1777.
3. Anselmi A, Aymami M, Tomasi J, et al. Durability of mitral valve replacement with a 3rd generation bioprosthesis. *Ann Thorac Surg*. March 2022;113(3):837-844.
4. Lehmann S, Merk DR, Etz CD, et al. Porcine xenograft for aortic, mitral and double valve replacement: long-term results of 2544 consecutive patients. *Eur J Cardiothorac Surg*. April 2016;49(4):1150-1156.
5. Chiariello GA, Beraud A-S, Vahdat O, et al. Late results after mitral valve replacement with Mosaic bioprosthesis in patients aged 65 years or younger. *Interact Cardiovasc Thorac Surg*. July 26, 2021;33(2):181-187.
6. Lorusso R, Miceli A, Gelsomino S, et al. Mitral Valve Replacement with a Third Generation Porcine Valve: An Italian Multicentered Study. *Ann Thorac Surg*. June 2020;109(6):18650-1872.
7. Yoshikawa Y, Okada Y, Okita Y, et al. Long-Term Outcomes of the Mosaic Mitral Porcine Bioprosthesis in Japan. *Circ J*. February 25, 2022;86(3):449-457.
8. Beute T, 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*. August 2020;110(2):508-515.
9. Celiento M, Blasi S, De Martino A, Pratali S, Milan AD, Bortolotti U. The Mosaic Mitral Valve Bioprosthesis: A Long-Term Clinical and Hemodynamic Follow-Up. *Tex Heart Inst J*. February 2016;43(1):13-19.
10. Riess FC, Fradet G, Lavoie A, Legget M. Long-term Outcomes of the Mosaic Bioprosthesis. *Ann Thorac Surg*. March 2018;105(3):763-769.
11. Uchino G, Murakami H, Mukohara N, et al. Modes of the bioprosthetic valve failure of the porcine and pericardial valves in the mitral position. *Eur J Cardiothorac Surg*. June 15, 2022;62(1):ezab506.
12. Weber PA, Jouan J, Matsunaga A, et al. Evidence of mitigated calcification of the Mosaic versus Hancock Standard valve xenograft in the mitral position of young sheep. *J Thorac Cardiovasc Surg*. November 2006;132(5):1137-1143.

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. Note: Manuals can be viewed using a current version of any major internet browser.

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