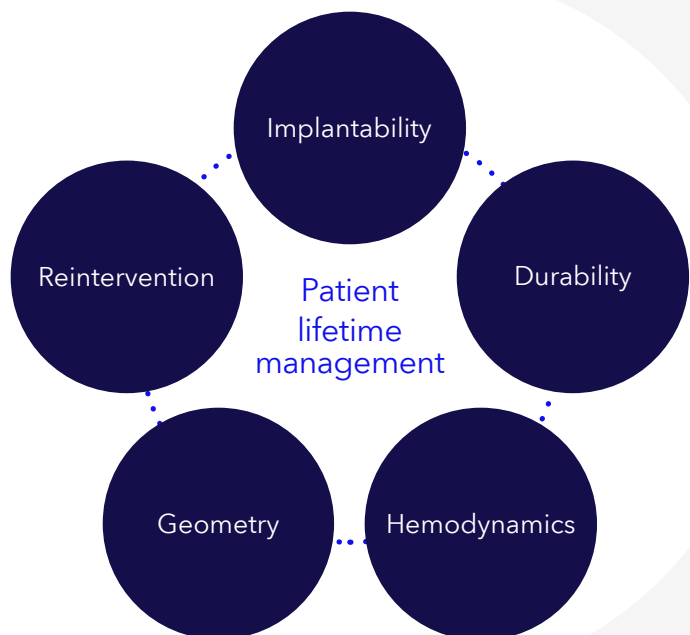


# Medtronic

Mosaic™ Mitral Bioprosthesis

## Built for a life. Time tested.

The Mosaic mitral bioprosthesis is based on more than 50 years of Medtronic's clinical experience with tissue valves. It's designed to provide long-term durability, smooth implantability, excellent hemodynamics and the potential for reintervention.



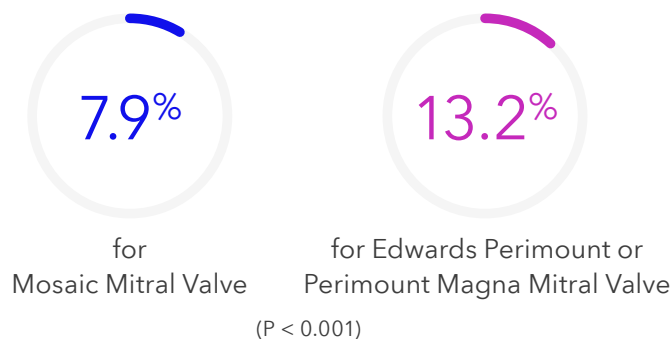
# Designed for extraordinary performance

## 1 Durability

The Mosaic surgical mitral valve demonstrates favorable long-term outcomes and **industry-leading durability**, supported by 16 years of published data – **unsurpassed among tissue valves**.<sup>1,2</sup>

### Long-term outcomes of Mosaic vs. Edwards<sup>TM\*</sup> pericardial mitral valve replacements<sup>1</sup>

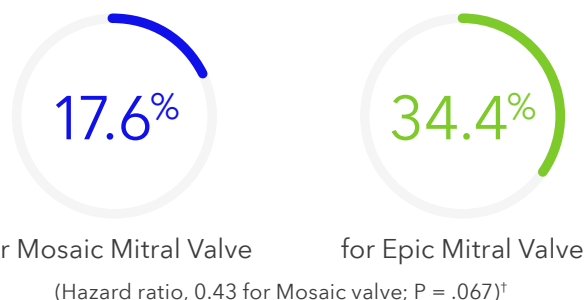
Cumulative incidence of reoperation for SVD at 15 years



[View the brochure »](#)

### Long-term outcomes of Mosaic vs. Epic<sup>TM\*</sup> mitral valve replacements<sup>3</sup>

Cumulative incidence of all reintervention with death as a competing risk at 10 years<sup>†</sup>



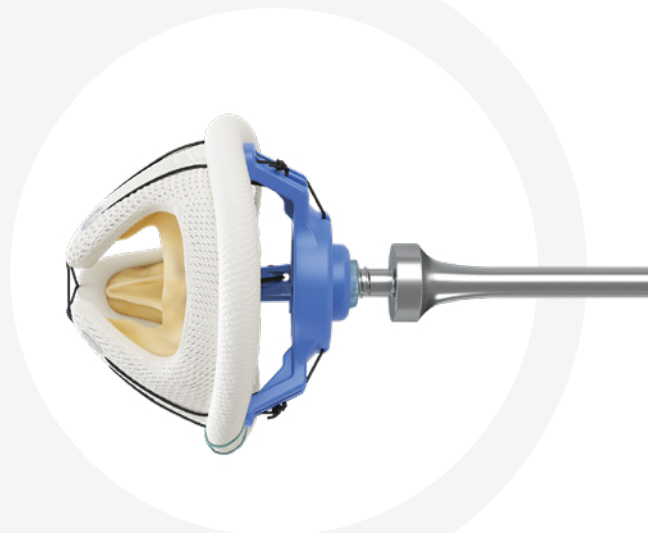
[Learn more »](#)

## 2 Implantability

The Cinch<sup>TM</sup> Implant System has a flexible stent to help facilitate valve implantation, especially in tight areas.

- Aids minimally invasive procedures
- Helps prevent suture looping
- Protects tissue from inadvertent damage
- Prevents entanglement with the sub-valvular apparatus

[View implantability details »](#)



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

## 3 Hemodynamics

The Mosaic mitral valve demonstrates excellent hemodynamics, with low gradients and large EOAs across all sizes.

**Clinical study hemodynamics at one year from respective clinical trials<sup>4,5</sup>**

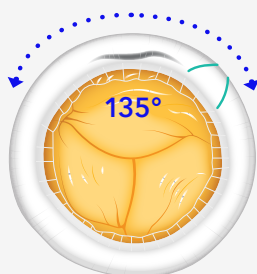
	Mosaic Mitral Valve	Epic/Epic Plus Mitral Valves
Mean gradient (mmHg) (n = )	4.5 (320)	5.2 (121)
Mean EOA (cm <sup>2</sup> ) (n = )	1.7 (288)	1.5 (79)

This chart is not intended to be a comparison of the two devices, as there is no head-to-head clinical study, but rather the intention is to illustrate the clinical results of the two similar trials. Multiple factors contribute to clinical study outcomes and need to be considered in making any assessments across different studies.

[Discover more »](#)

## 4 Geometry

The Mosaic valve reflects the asymmetry of the native porcine valve. The largest leaflet of the Mosaic valve is intended to align with the patient's anterior mitral leaflet to help accommodate ventricular flow.



The asymmetrical design of the Mosaic valve offers one wider leaflet spaced at 135°



The wider leaflets also offers a large intercommissural distance (example of Mosaic valve size 29mm)

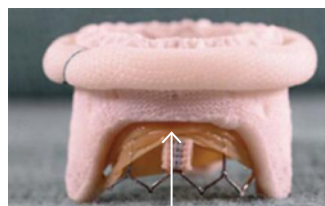
[View geometry details »](#)

## 5 Reintervention

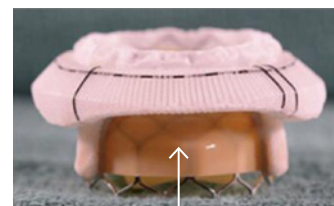
The design of the Mosaic mitral valve makes it suitable for future valve-in-valve (ViV) procedures.

"Testing indicates a tendency for porcine valve leaflets to crumple, compared with pericardial valve leaflets, which remain rigid and upright. Pericardial valve leaflets are also longer and likely to cover more surface area of the TMVR stent."<sup>7</sup>

**Mosaic Mitral Valve<sup>8</sup>    Magna Mitral Ease Valve<sup>8</sup>**



Native porcine tissue leaflets "crumple"



Bovine pericardial tissue leaflets "curtain"

## 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*. August 2020;110(2):508-516.
- <sup>2</sup> Riess FC, Fradet G, Lavoie A, Legget M. Long-term outcomes of Mosaic bioprosthesis. *Ann Thorac Surg*. 2018;105(3):763-769.
- <sup>3</sup> Tomsic A, Marin-Cuatas M, De La Cuesta M, et al. Clinical Outcomes After Mitral Valve Replacement With Epic and Mosaic Bioprosthetic Valves. *Ann Thorac Surg Short Reports*. Published online December 2023.
- <sup>4</sup> Instructions for Use: Stented Porcine Tissue Valves Epic™/Epic™ Supra. St. Jude Medical, Inc. Available at: [https://www.accessdata.fda.gov/cdrh\\_docs/pdf4/P040021S004c.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040021S004c.pdf). Accessed April 20, 2023.
- <sup>5</sup> Mosaic Porcine Bioprosthesis. Instructions for Use. Medtronic, Inc. 2018. 1220016001 Rev. 1C.
- <sup>6</sup> Data on file at Medtronic. Report #D00807486\_A, July 28, 2022.
- <sup>7</sup> Reid A, Zekry B, Turaga M, et al. Neo-LVOT and Transcatheter Mitral Valve Replacement. *JACC Cardiovasc Imaging*. 2021;14:854-866.
- <sup>8</sup> Bapat V, Pirone F, Kapetanakis S, et al. Factors Influencing Left Ventricular Outflow Tract Obstruction Following a Mitral Valve-in-Valve or Valve-in-Ring Procedure, Part 1. *Catheter Cardiovasc Interv*. 2015;86:747-760.

## 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.

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