

Medtronic

Not all porcine tissue valves are designed the same.



Hemodynamic performance is impacted.

The Mosaic™ bioprosthesis was designed to allow for maximum blood flow. The creation of the valve – from the porcine leaflets and valve geometry (specifically stent height), to how the tissue is mounted in the frame – affects how optimally the blood flows in diastole, and how well the leaflets coapt in systole.



The Mosaic mitral valve demonstrates low gradients and large EOAs.

Clinical study hemodynamics at one year from respective clinical trials^{1,2}

	Epic™/Epic Plus mitral ¹				
Size	25	27	29	31	33
Mean gradient (mm) (n =)	NA	6.1 ± 2.9 (30)	5.5 ± 1.7 (41)	4.8 ± 1.4 (26)	4.1 ± 1.6 (24)
Mean EOA (cm ²) (n =)	NA	1.4 ± 0.7 (16)	1.5 ± 0.5 (26)	1.6 ± 0.3 (15)	1.5 ± 0.3 (22)

	Mosaic mitral ²				
Mean gradient (mm) (n =)	5.7 ± 1.7 (41)	4.6 ± 2.1 (98)	4.4 ± 1.8 (123)	3.7 ± 1.4 (50)	3.4 ± 1.8 (8)
Mean EOA (cm ²) (n =)	1.6 ± 0.4 (35)	1.7 ± 0.5 (90)	1.8 ± 0.5 (114)	1.7 ± 0.5 (43)	1.9 ± 0.5 (6)

The charts are not intended to be a comparison of the two devices, as there is no head-to-head clinical study, but rather are intended 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.

Epic™ tissue mounting technique reduces the space available for flow.³

The tissue mounting technique used for the Epic valve places part of each cusp's aortic wall (Figure 1) into the stent lumen – important space needed for flow and reducing the potential “true” inside diameter (ID). (Figure 2)

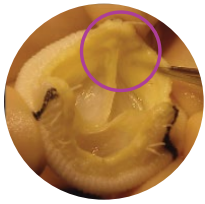


Figure 1
Retained excess
aortic wall



Figure 2
Retained excess
aortic wall
protruding into
flow area

Impact of stent height on hemodynamics

The Evin, et al. study⁴ was conducted to establish in vitro nominal reference EOA values and transvalvular gradients independent of manufacturers.

A key finding was that EOAs increased and gradients decreased with increasing bioprosthesis height. EOAs and gradients were also impacted by prosthesis diameter, stent diameter, and heart rate.

Figure 1

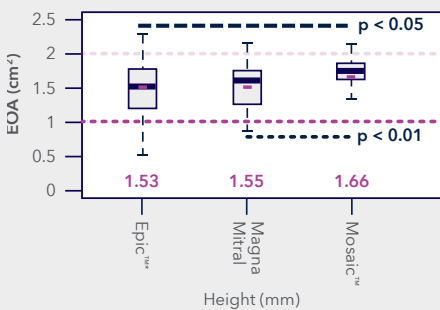
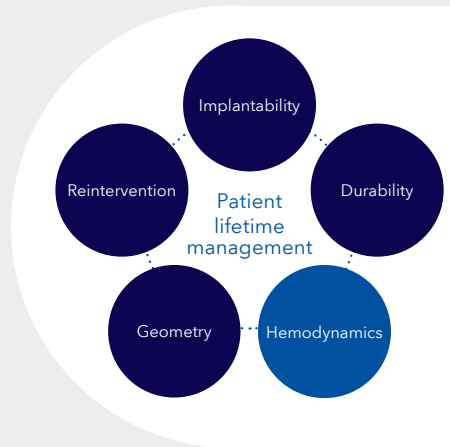
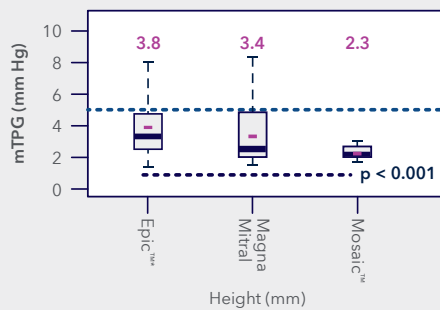


Figure 2



¹ 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. Accessed April 20, 2023.

² Mosaic Porcine Bioprosthesis. Instructions for Use. Medtronic, Inc. 2018. 1220016001 Rev. 1C.

³ Data on file.

⁴ Evin M, Magne J, Grieve S, Rieu R, Pibarot P. Characterization of Effective Orifice Areas of Mitral Prosthetic Heart Valves: An In-Vitro Study. *J Heart Valve Dis.* November 2017;26(6):677-687.

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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