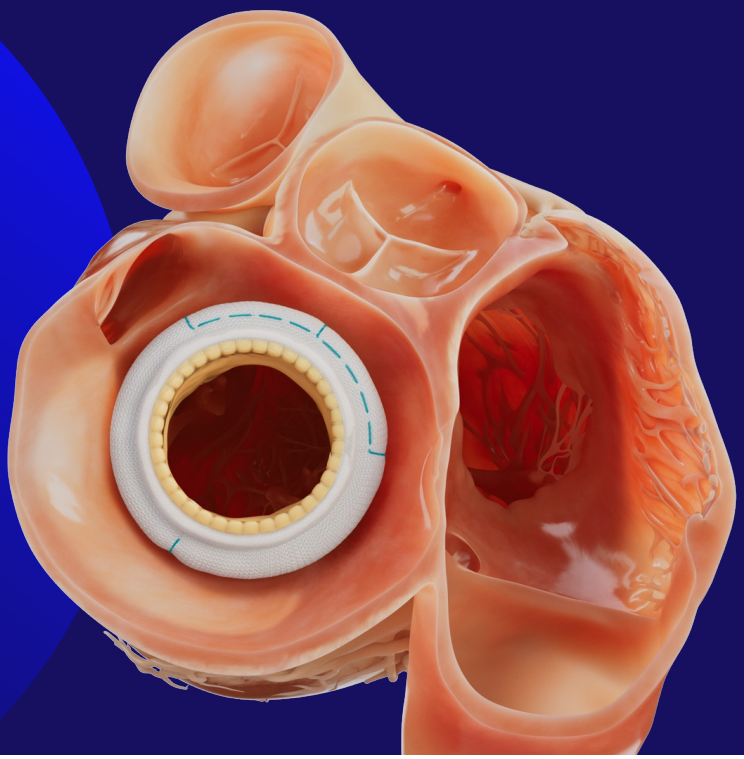
Medtronic

Not all porcine mitral valves are designed the same.



Mosaic Neo™ mitral bioprosthesis

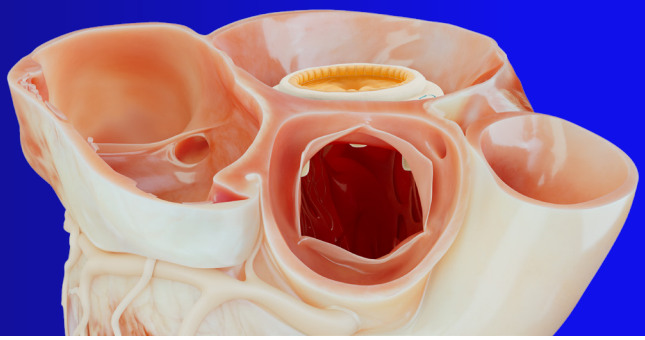
Intuitive by design.
Proven to perform.

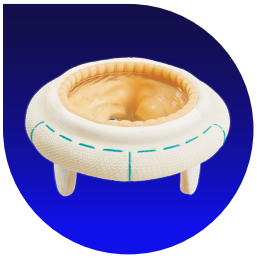
Recent long-term studies have shown that porcine tissue valves demonstrated better durability outcomes in the mitral position than bovine pericardial tissue valves.[1-3] However, it's important to remember that there are differences between commercially available porcine mitral valves in clinical performance and lifetime management.

Learn how the Mosaic Neo mitral bioprosthesis is designed to support long-term performance and lifetime management.

The Mosaic Neo mitral bioprosthesis is created for LVOT clearance.

Studies have shown that risk for left ventricular outflow tract (LVOT) obstruction is multifactorial,[4,5] which is why the Mosaic Neo valve was thoughtfully designed to protect the neo-LVOT.[6]





The atrialized design of the Mosaic Neo valve reduces left ventricular (LV) protrusion by up to 23%, compared to the legacy Mosaic™ mitral bioprosthesis, to enable LVOT clearance.[7,8]

Thanks to its native-porcine design, the Mosaic Neo mitral valve offers one wider leaflet spaced at 135°. Compared to competitive valves, this wider distance between the stent posts at the anterior annulus enables LVOT clearance and accommodates ventricular flow.[†,9–11]

To aid with correct valve positioning and enable LVOT clearance, the cuff markers are designed to easily identify the largest leaflet.[11,12]

The Mosaic Neo mitral valve offers an easy-to-identify landing zone for future mitral valve-in-valve procedures and a larger inner diameter compared to the Epic™* Plus valve for same labelled valve sizes.[‡,6,7,12,13]

† Compared to Abbott and Edwards Lifesciences mitral valves commercially available in the United States. Bench test, may not be indicative of clinical performance.

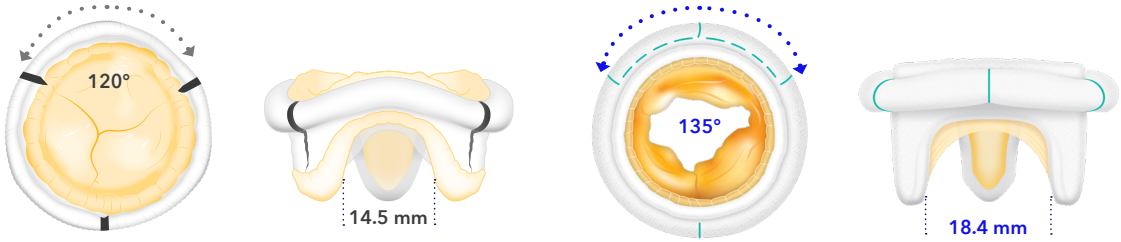
‡ Dimensional measurements taken with Mosaic Neo valve size 29, Epic Plus size 29 based on OD comparability.

Consider a holistic approach to LVOT clearance and lifetime management.

Studies have shown that a wide distance between the anterior stent posts can reduce the risk for LVOT obstruction.[5] Additionally, implanting a transcatheter mitral valve-in-valve in a prosthesis with a smaller diameter can result in suboptimal function and higher gradients.[13] These dimensions are sometimes overlooked when discussing lifetime management of mitral valve disease; however, there are important design differences between the Mosaic Neo mitral valve and the Epic Plus mitral valve that need to be taken into consideration.

One wider leaflet spaced at 135°

The native-porcine design of Mosaic Neo offers one wider leaflet spaced at 135° – putting the stent posts more toward the edge of the LVOT[9–11] and allowing for a **27% wider distance between the stent posts compared to the Epic Plus valve.**[†,‡,§,10]

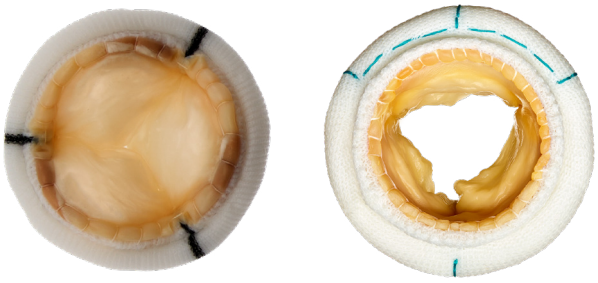


Epic™* / Epic Plus valve
Size 29 mm

Mosaic Neo mitral valve
Size 29 mm

Larger inner diameter compared to Epic Plus

In addition, **the Mosaic Neo valve offers a larger inner diameter compared to Epic Plus for the same labelled valve sizes,** which may enable implantation of larger transcatheter mitral valves in potential future valve-in-valve procedures.[§,6,7,13]



Epic Plus valve | **Mosaic Neo mitral valve**

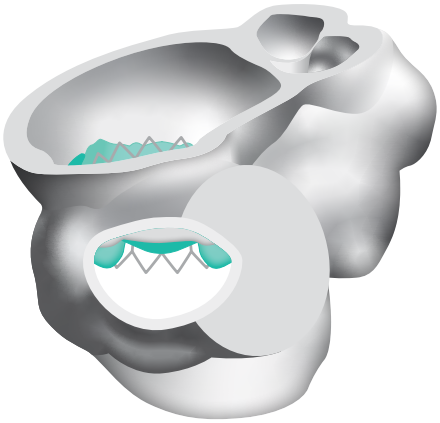
	Epic Plus valve size 29 mm	Mosaic / Mosaic Neo valve size 29 mm
Measured inner diameter incl. tissue (cone gauge)	23.02 mm (95% CI 22.81–23.2 mm)	24.15 mm (95% CI 24.06–24.24 mm)

† 3D patient model, native annulus diameter 30.8 mm, aorta-mitral-annular angle 120 degrees. Medtronic anatomical model D00807491_A 3D. Dimensional measurements taken with Mosaic Neo valve size 29, Epic Plus valve size 29 based on dimensional comparability.
‡ Bench test, may not be indicative of clinical performance.
§ Medtronic data on file. D01140689_A_EN. Design characterization report. Dimensions and measurements taken with Mosaic mitral size 29, Epic mitral valve size 29 based on dimensional comparability.

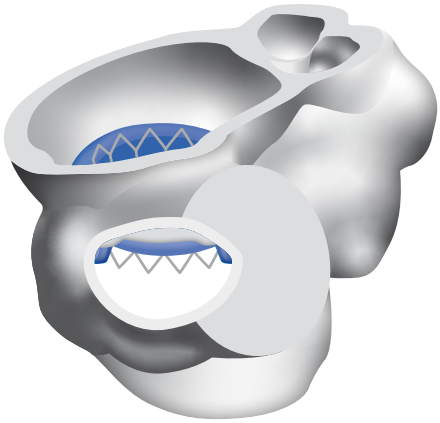
Designed for LVOT clearance and lifetime management

Unlike other valves, the Mosaic Neo mitral valve combines a reduced left ventricular stent post protrusion,[7,8] a unique wide anterior distance between the stent posts,[†,9–11] intuitive orientation markers,[7,14,15] and an easy-to-identify landing zone under fluoroscopy to enable LVOT clearance and preservation of the neo-LVOT.[‡,12]

See how the Mosaic Neo mitral valve and the Epic Plus mitral valve compare when implanted virtually into the same patient.[§]



Epic Plus mitral valve
Size 29 mm



Mosaic Neo mitral valve
Size 29 mm

† Compared to Abbott and Edwards Lifesciences mitral valves commercially available in the United States. Bench test, may not be indicative of clinical performance.

‡ The benefits of the Mosaic Neo valve atrialized design have been demonstrated through bench testing. No direct clinical evaluation in humans has been conducted.

§ 3D patient model, native annulus diameter 30.8 mm, aorta-mitral-annular angle 120 degrees. Medtronic anatomical model D00807491_A 3D. Dimensional measurements taken with Mosaic Neo valve size 29, Epic Plus valve size 29 based on dimensional comparability.

Hemodynamics

The native-porcine Mosaic Neo valve offers low gradients and large EOAs across all sizes, as demonstrated by the Mosaic mitral valve.[16] The composite-porcine Epic tissue-mounting technique reduces the space available for flow.[17]

Recent guidelines state that a mitral valve EOA of ≤ 1.5 cm^2 in conjunction with clinical factors (symptoms, high risk of thromboembolism, or hemodynamic decompensation) is indicative of clinically severe mitral stenosis.[18,19]

Hemodynamics at one year from respective IFUs

Epic/Epic Plus mitral at one year[20]

Size (mm)	25	27	29	31	33
Mean gradient (mmHg)	N/A	6.1 ± 2.9 (n = 30)	5.5 ± 1.7 (n = 41)	4.8 ± 1.4 (n = 26)	4.1 ± 1.6 (n = 24)
Mean EOA (cm^2)	N/A	1.4 ± 0.7 (n = 16)	1.5 ± 0.5 (n = 26)	1.6 ± 0.5 (n = 15)	1.5 ± 0.3 (n = 22)

Mosaic mitral valve at one year[21]

Size (mm)	25	27	29	31	33
Mean gradient (mmHg)	5.7 ± 1.7 (n = 41)	4.6 ± 2.1 (n = 98)	4.4 ± 1.8 (n = 123)	3.7 ± 1.4 (n = 50)	3.4 ± 1.8 (n = 8)
Mean EOA (cm^2)	1.6 ± 0.4 (n = 35)	1.7 ± 0.5 (n = 90)	1.8 ± 0.5 (n = 114)	1.7 ± 0.5 (n = 43)	1.9 ± 0.5 (n = 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.

Key risks associated with the use of bioprosthetic heart valves include: structural deterioration, nonstructural dysfunction, endocarditis, and surgical complications, including stroke and death.

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15. Medtronic data on file. D01187247 Rev. E. Design description document.
16. Medtronic data on file. M071154C001DOC1 Rev. A. Mosaic Neo mitral bioprosthesis Clinical Study Summary.
17. Medtronic data on file. St. Jude porcine valve evaluation report, created 01/2005.
18. Praz F, Borger MA, Lanz J, et al. 2025 ESC/EACTS guidelines for the management of valvular heart disease. *Eur Heart J.* 2025;46(44):4635–4736.
19. Otto CM, Nishimura RA, Bonow RO, et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2021;143(5):e72-e227.
20. Epic Plus instruction for use. ARTEN600181537 F.
21. 1220016001 Rev 1C. Mosaic bioprosthesis instructions for use.

Mosaic™ bioprosthesis

Indications: The Mosaic bioprosthesis are indicated for the replacement of malfunctioning native or prosthetic aortic and/or mitral heart valves.

Contraindications: No contraindications for use of this device are 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 dysrhythmias, death, endocarditis, heart failure, hemolysis, hemolytic anemia, anticoagulant/antiplatelet-related hemorrhage, infection other than endocarditis, transvalvular or paravalvular leak, myocardial infarction, nonstructural dysfunction (obstructive pannus ingrowth, suture dehiscence, inappropriate sizing, other), stroke, structural deterioration (calcification, leaflet tear, other), thromboembolism, and valve thrombosis. It is possible that these complications could lead to reoperation, explantation, permanent disability, or death.

Mosaic Neo™ mitral bioprosthesis

Indications: The Mosaic Neo mitral bioprosthesis is indicated for the replacement of a malfunctioning native or prosthetic mitral heart valve.

Contraindications: No contraindications for use of this device are known.

Warnings/Precautions/Adverse Events: As with any implanted medical device, there is potential for patient immunological response, including an allergic response. Care should be exercised in patients with hypersensitivities to the device materials, such as nickel. Calcific degeneration could cause accelerated deterioration of the valve in patients with altered calcium metabolism (for example, chronic renal failure, hyperparathyroidism). Calcification may occur earlier in children, adolescents, or young adults. Premature calcification may also occur in older adults who accept a biologic prosthesis. Patients with a bioprosthesis that require chronic anticoagulation are at additional risk of bleeding. Stenosis and regurgitation of the bioprosthesis may occur in patients with coagulation disorders such as AT3 deficiency. Paravalvular leak is more likely to occur in patients with aneurysmal aortic or degenerative conditions, cystic medial necrosis, or Marfan syndrome. Adverse events can include: allergic reaction/immunologic response, aneurysm or pseudoaneurysm, aortic tissue damage, cardiac arrest, cardiac arrhythmias, cardiac tamponade, embolism or thromboembolism, endocarditis, heart block, heart failure, hemodynamic instability, hemolysis, hemolytic anemia, anticoagulant/antiplatelet-related hemorrhage, hypertension or hypotension, inflammatory reaction, infection other than endocarditis, transvalvular or paravalvular leak, mitral tissue damage, myocardial infarction, nonstructural dysfunction (leaflet entrapment/impingement, obstructive pannus ingrowth, suture dehiscence, inappropriate sizing), pericardial effusion, pleural effusion, prosthesis regurgitation, prosthesis stenosis, stroke, structural deterioration (calcification, leaflet tear), thrombus or thrombosis. These complications could lead to reoperation, explant of the bioprosthesis, permanent disability or organ damage, or death.

For a listing of indications, contraindications, precautions, warnings, and potential adverse events, please refer to the Instructions for Use (IFU).
If applicable, consult electronic IFUs (eIFUs) at medtronic.com/manuals.

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

This material should not be considered the exclusive source of information, it does not replace or supersede information contained in the device manual(s). Please note that the intended use of a product may vary depending on geographical approvals. See the device manual(s) for detailed information regarding the intended use, the (implant) procedure, indications, contraindications, warnings, precautions, and potential adverse events. For an MRI compatible device(s), consult the MRI information in the device manual(s) before performing an MRI. If a device is eligible for eIFU usage, instructions for use can be found at Medtronic's website manuals.medtronic.com. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser. Medtronic products placed on European markets comply with EU and UK legislation (if applicable) on medical devices. For any further information, contact your local Medtronic representative and/or consult Medtronic's websites.

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