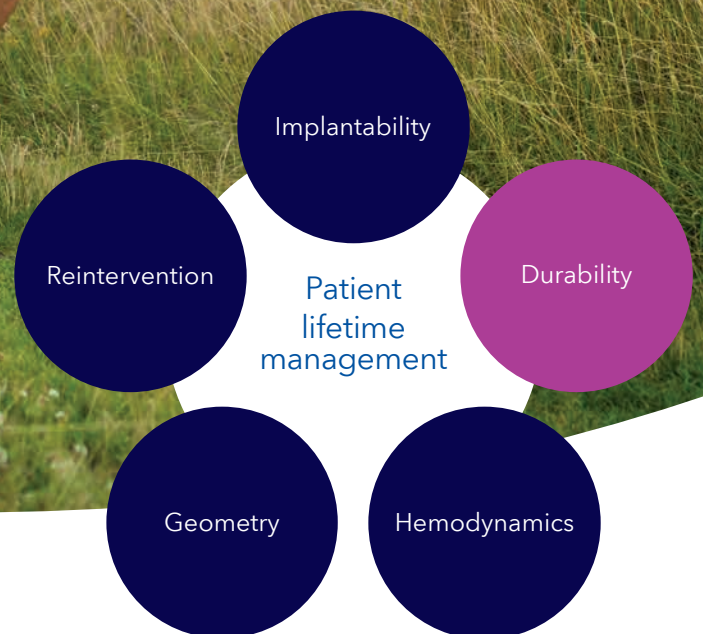


Medtronic



Mosaic™ Bioprosthesis

Unsurpassed  
durability

# Durability of mitral bioprostheses:

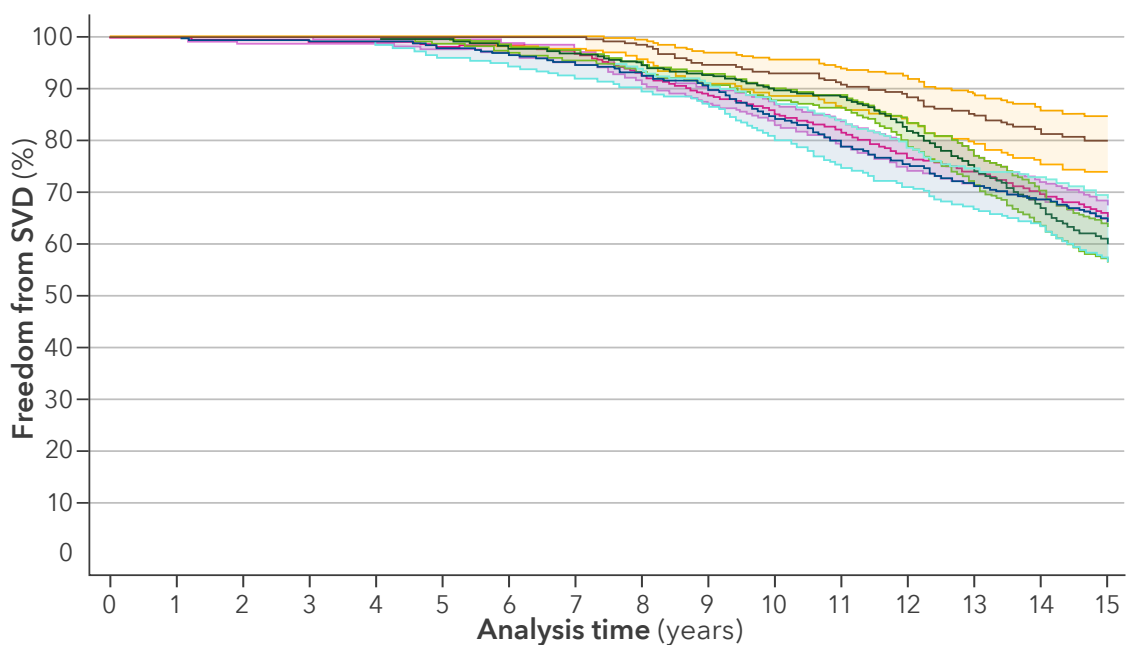
## A meta-analysis of long-term follow-up studies

### Methods

- This is a meta-analysis undertaken to compare SVD risk of porcine and pericardial valves in the mitral position.
  - 1,570 papers were identified and 40 were reviewed after criteria was applied.
  - More than 15,000 patients were included.
  - Four valve types with data after 1980 were selected for the analysis: Carpentier-Edwards™\* (CE) porcine (1,361), Hancock™ II (424), Mosaic (940), and CE pericardial (1,143).
- The majority of studies defined SVD according to the STS/AATS guidelines.

### Results

- The Mosaic valve showed the lowest rate of SVD.
  - At 15 years, freedom from SVD was highest for Mosaic, followed by Hancock II, CE porcine, then CE pericardial.
  - Across similarly aged patients, freedom from SVD was higher in porcine valves compared to bovine pericardial valves.
  - CE bovine pericardial valve demonstrated significantly higher risk of SVD compared to the CE porcine valve, which is no longer distributed.



Source: Malvindi PG, Mastro F, Kowalewski M, et al. Durability of Mitral Valve Bioprostheses: A Meta-Analysis of Long-Term Follow-Up Studies. *Ann Thorac Surg.* February 2020;109(2):603-611.

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

17-year follow-up of 940 implants

## Methods

This retrospective study compared the long-term outcomes of Mosaic porcine mitral valves to Carpentier-Edwards bovine pericardial mitral valves.

- Study design:

- Retrospective, observational, single-center study
- 463 Mosaic mitral porcine bioprosthesis
- 477 CE mitral pericardial bioprosthesis (majority Perimount Magna mitral)
- 401 of each valve were propensity matched
- Patient characteristics:
  - Average age for Mosaic = 68.6 years
  - Average age for Perimount = 67.7
- STS and AATS jointly defined SVD as dysfunction or deterioration involving the operated valve, exclusive of infection or thrombosis, as determined by reoperation, autopsy, or clinical investigation.

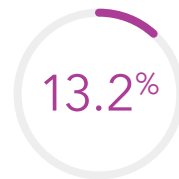
## Results

- 37% of Mosaic valves failed by stenosis and 63% for regurgitation versus 96% of pericardial valves failed by stenosis.
- None of the reoperative patients required emergent reintervention.

## Cumulative incidence of reoperation at 15 years ( $P < 0.001$ ):



for  
Mosaic Mitral



for CE Perimount or  
Perimount Magna Mitral



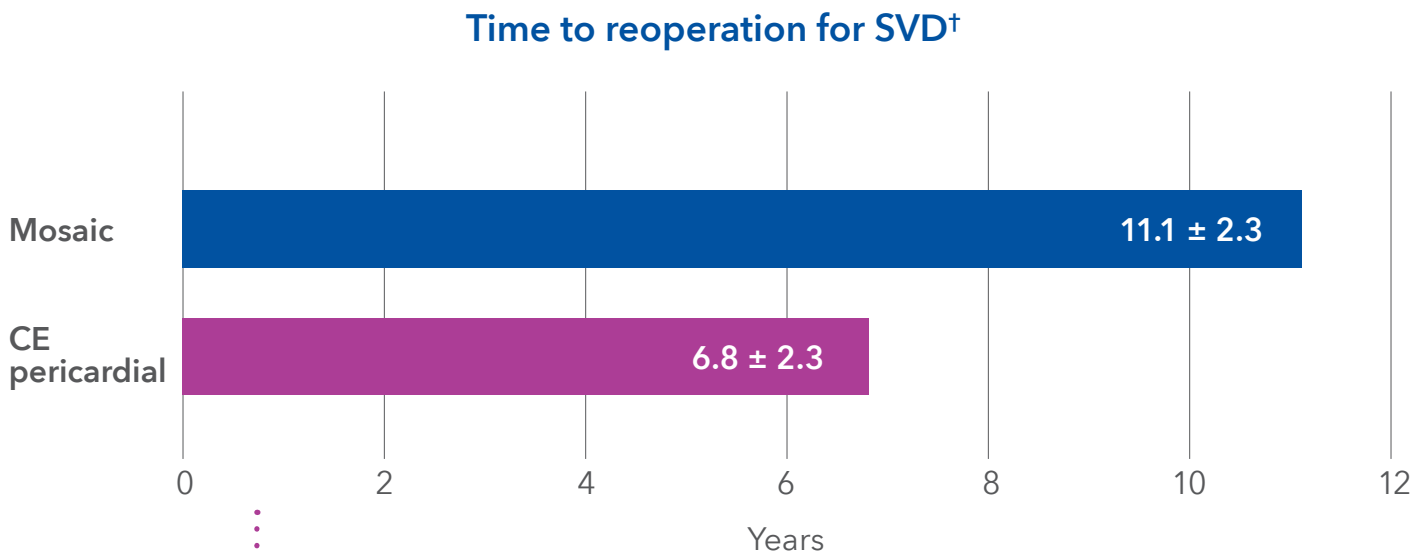
Source:

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):508-515.

<sup>TM\*</sup>Third-party brands are trademarks of their respective owners.

# Long-term outcomes of Mosaic versus Perimount mitral replacements

17-year follow-up of 940 implants (cont'd.)



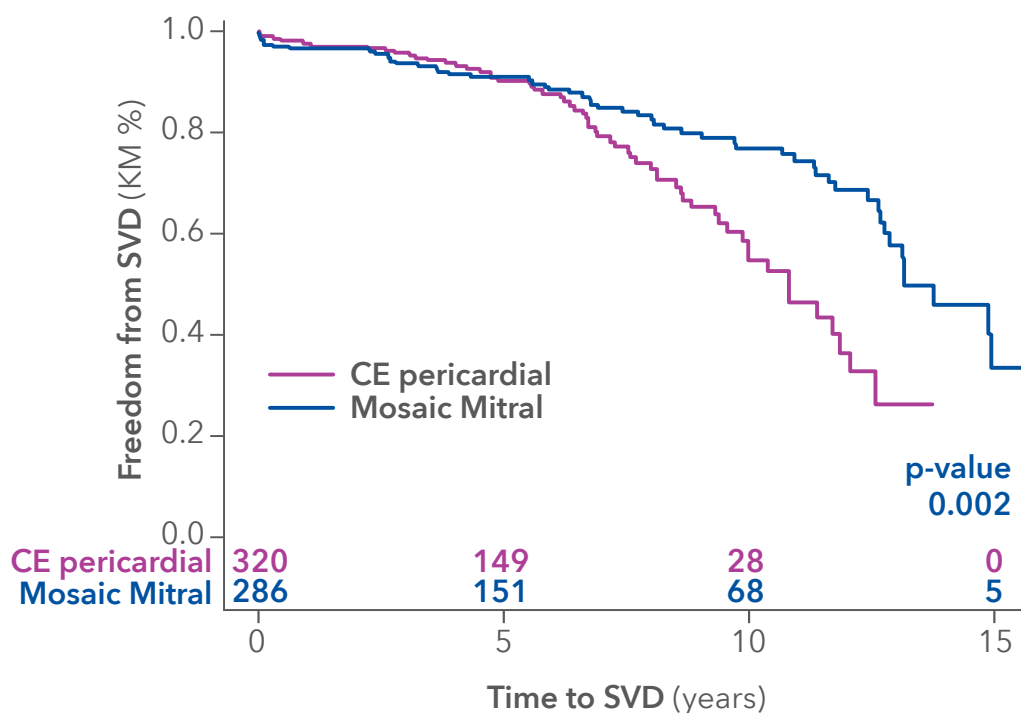
On average, the time before reoperation for SVD was 4.3 years longer with Mosaic porcine valves than Edwards pericardial valves.



<sup>†</sup>SVD was defined, according to STS, as dysfunction or deterioration involving the operated valve, exclusive of infection or thrombosis, as determined by reoperation, autopsy, or clinical investigation. Mean follow-up times were significantly different (Mosaic: 7.0 ± 4.8 versus Edwards: 6.0 ± 3.9,  $p = 0.002$ ).

Source:  
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):508-515.

## 17-year follow-up of 940 implants (cont'd.)



In the matched patient cohort, survival at 15 years was not significantly different between the two groups; nevertheless, the cumulative incidence of reoperation for structural valve deterioration was significantly lower in the Mosaic group. **For patients less than age 65 years, SVD at 15 years was 15.8% versus 30.2% for porcine and pericardial valves respectively (p = 0.009).**

The rate of overall reoperation for pericardial valves is 1.89 (95% CI 1.13%–3.17%) times higher than that for porcine valves.

The rate of reoperation due to SVD is 2.32 (95% CI 1.31–4.11) times higher in the pericardial valves versus the porcine valves.



# Take a closer look: Mosaic and Mitris™\* IFU data

## Mosaic IFU PMA trial

365   
Number of patients

68  
Average age

### Freedom from SVD:



## Mitris IFU PMA trial

82   
Number of patients

68  
Average age

### Freedom from SVD:



These 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 two trials. Multiple factors contribute to clinical study outcomes and need to be considered in making any assessments across different studies.

# Mosaic: Built for a life

Younger patients are opting for tissue valves to avoid taking warfarin as needed with a mechanical heart valve. Traditionally, tissue valves fail earlier and more often in the younger patient population; so the following studies have evaluated the performance of the Mosaic Mitral valve in younger patients specifically:

- Riess<sup>1</sup>: This study demonstrates acceptable long-term rates of death, reoperation, and explant due to SVD with the Mosaic bioprosthesis implanted in either the aortic or mitral position. Freedom from explant due to SVD was not significantly different between patients younger than 60 years or 60 years and older in the mitral cohort at 16 years.
- Beute<sup>2</sup>: In the series of bioprosthetic mitral valve replacements, rates of reoperation due to SVD were higher in patients < 65 years old compared to older patients both for Mosaic Mitral and CE Perimount. However, structural valve deterioration requiring reoperation occurred earlier and more frequently in the CE Perimount bovine pericardial valves than in the Medtronic Mosaic porcine valves when implanted in patients < 65 years old.
- Chiariello<sup>3</sup>: Mosaic mitral bioprosthetic implants showed acceptable results in younger patients. These results obtained in a younger patient population confirm that Mosaic is a reliable prosthesis even when employed in the < 65-year-old patients.



<sup>1</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>2</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):508-515.

<sup>3</sup>Chiariello GA, Beraud AS, 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.

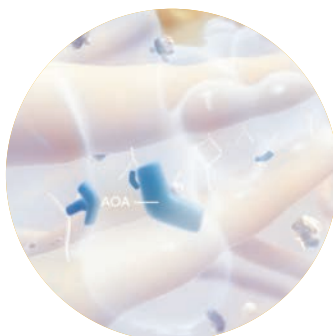
# Time tested

The Medtronic-patented AOA™ tissue treatment that utilizes amino oleic acid is used across a suite of Medtronic devices to help drive durability, valve replacement and patient lifetime management. Clinical use with these devices encompasses more than half a million patients for over 30 years.†



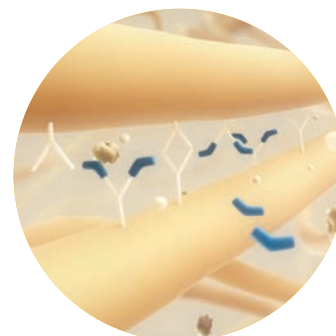
## After fixation

- Free aldehydes present



## After fixation

- AOA covalently bonds with free aldehydes
- Lipids are washed away
- Subsequent storage in glutaraldehyde allows any remaining free aldehydes to crosslink



## After treatment

- Large AOA molecules slow diffusion of calcium into tissue matrix



Mosaic™ Bioprosthesis  
Aortic and Mitral‡



Freestyle™ Aortic  
Bioprosthesis‡



Avalus™ Aortic  
Bioprosthesis‡



CoreValve™  
Evolut™ Platform§

†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.

‡Surgical valve replacement risks may include infection, surgical complications, stroke, endocarditis, and death.

§TAVR risks may include, but are not limited to, death, stroke, damage to the arteries, bleeding, and need for permanent pacemaker.

### 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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