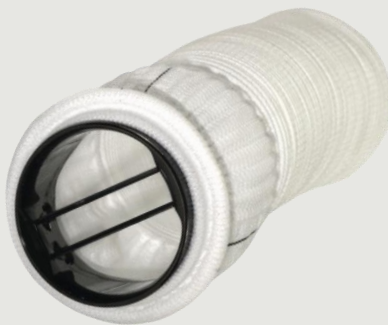


On-X[®] Heart Valve Solutions Overview



On-X[®]
Aortic Heart Valve



On-X[®]
Ascending Aortic Prosthesis



On-X[®]
Mitral Heart Valve

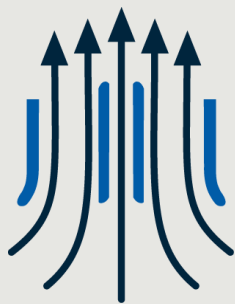
Pinnacle of Valve Material & Design

Better Laminar Flow

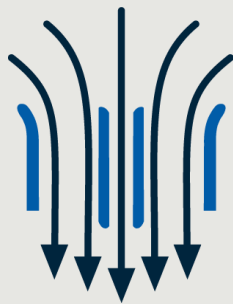
On-X[®] Aortic and Mitral Valves

90° Opening

On-X Aortic and Mitral Valves have leaflets that can open 90° to promote better laminar flow.



Aortic



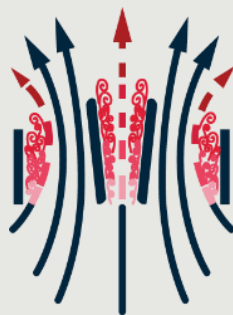
Mitral

VS

All Other Bileaflet Aortic and Mitral Valves

< 90° Opening

All other bileaflet aortic and mitral valves have leaflets that can only open 78° to 85°. ¹⁻⁴



Aortic



Mitral

1. Medtronic Open Pivot Heart Valve Instructions for Use, M951905A001 Rev. 1A (2013). 2. Kandemir O et al., St. Jude Medical and CarboMedics mechanical heart valves in the aortic position comparison of long term results. Tex Heart Inst J. 2006; 33: 154–159. 3. Shipkowitz T et al., inventor, 2001 Jan. 23. Leaflet positioning for a mechanical heart valve. United States patent 6,176,876 B1. 4. CarboMedics Prosthetic Heart Valve Instructions for Use, 226-07ED003L (1997-02).

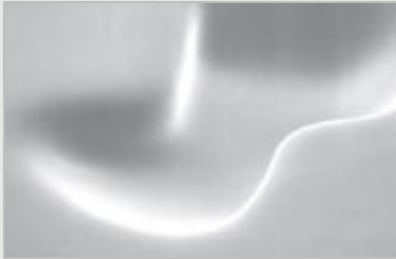
Reduced Thrombogenicity

On-X®

Aortic and Mitral Valves

Smoother Surface

On-X Aortic and Mitral Valves have a smoother surface¹ on the entire body and leaflets to reduce thrombogenicity.²



Smooth Pivot²



Pure Pyrolytic Carbon²

VS

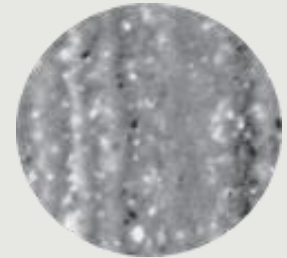
All Other Bileaflet Aortic and Mitral Valves

Rougher Surface

All other bileaflet aortic and mitral valves have rougher surfaces¹ that are more thrombogenic.²



Rough Machined Pivot²



Silicon Alloyed
Pyrolytic
Carbon²

1. More R and Haubold A. Surface chemistry and surface roughness of clinical pyrocarbons. Cell Mater. 1996;6: 273-79. 2. LaGrange L et al., Compatibility of carbon and blood. Hegyeli RJ, Editor, Proceedings, Artificial Heart Program Conference, Washington, DC, June 9-13, 1969, 47-58.

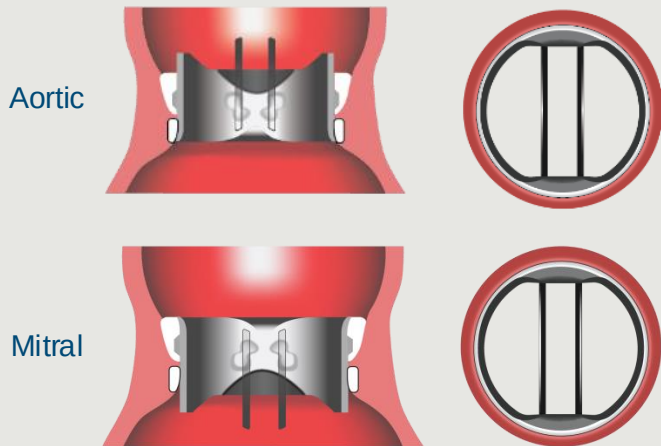
Complete Annulus Support

On-X®

Aortic and Mitral Valves

Complete Annulus Support

On-X Aortic and Mitral Valves have leaflet guards and a flared inlet designed to prevent pannus, encroachment of the subvalvular apparatus, and conceal pledgets.

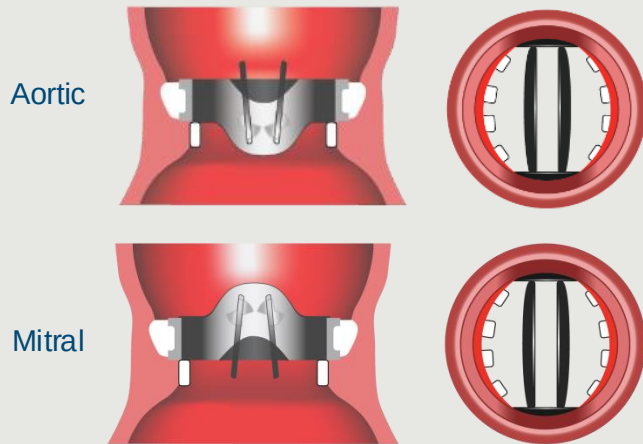


VS

All Other Bileaflet Aortic and Mitral Valves

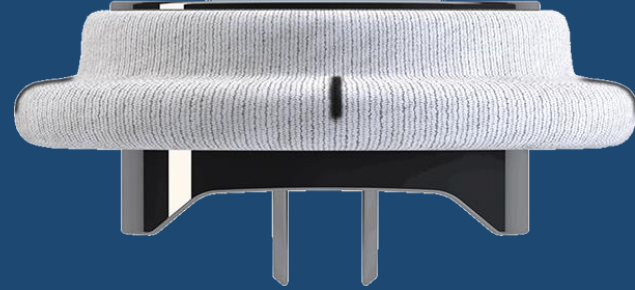
Incomplete Annulus Support

All other bileaflet aortic and mitral heart valves have unprotected inlets, allow pannus, and exposes pledgets.



ARTIVION™

On-X[®] Mitral Heart Valves



ARTIVION[®]

On-X[®] Mitral Heart Valve

4.6mmHG AVERAGE MEAN GRADIENT

On-X Mitral demonstrates excellent hemodynamics sustained out to 5 years, with an average mean gradient of **4.6mmHG** across all valve sizes.¹

ARTIVION[®]

1. Ruel M, et al. Midterm survival, clinical, and hemodynamic outcomes of a novel mechanical mitral valve prosthesis. J Thorac Cardiovasc Surg (2024), doi: <https://doi.org/10.1016/j.jtcvs.2024.11.029>.

On-X[®] Mitral Valve: Redefining Size. Performance.



Standard

Optimal 2.1 cm² Effective Orifice Area (EOA)
Produces Exceptional ≤ 4.4 mmHg Mean Gradients
Across all Valve Sizes ≥ 25 mm.¹

Reduce the Risk of Prosthesis-Patient Mismatch
(PPM) Through Improved Hemodynamics.²



Conform-X

- 1 90° leaflets:**¹ promotes laminar flow
- 2 Pure pyrolytic carbon:** reduces thrombogenicity²
- 3 Flared inlet:** prevents pannus; organizes flow
- 4 Universal valve housing:** Exceptional hemodynamics and optimal size

On-X[®] Mitral Valve: Survival

The On-X Mitral Heart Valve, which is engineered for exceptional clinical performance, now has the most robust body of evidence supporting its use as demonstrated by the low mortality rates in PROACT Mitral¹.

- The PROACT Mitral Study¹ data showed patients with standard-dose anticoagulation had excellent survival rates of 99.5% at 1 year, 94% at 3 years and 91% at 5 years. (Figure 1)
- These results also complement other large-scale analysis such as Goldstone et al.² that show in patients up to 70 years of age, mechanical mitral valves have a survival benefit at 15 years over tissue valves. (Figure 2)
- This evidence continues to support the 2020 AHA/ACC and 2021 ESC/EACTS Guidelines,^{3,4} which recommend the use of a mechanical mitral prosthesis for patients < 65 y/o.

Figure 1

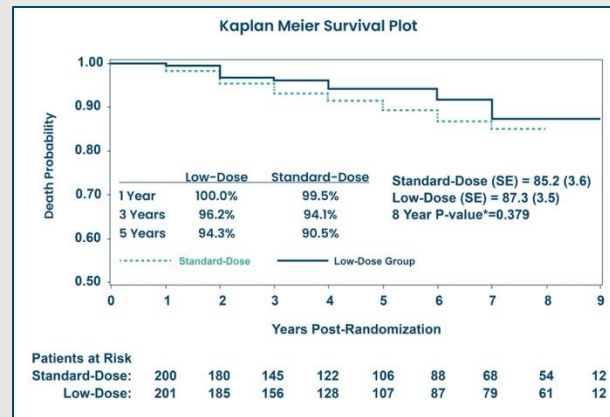
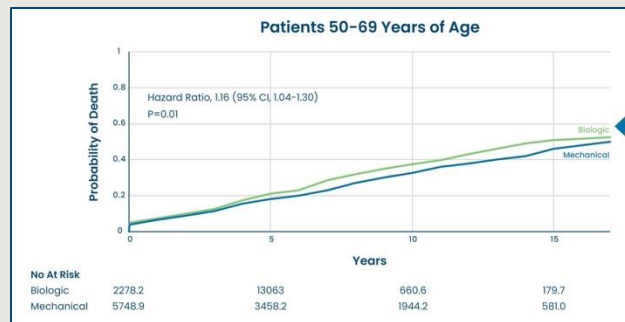


Figure 2



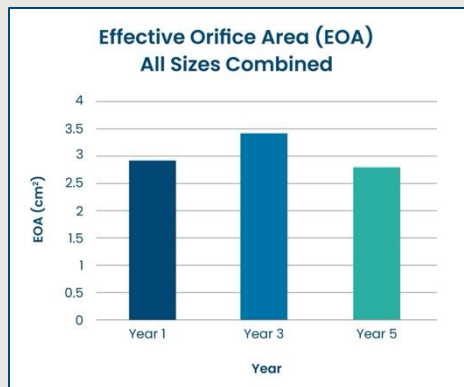
1. Chu M.W.A., et al. (2023). Low-Dose Vs Standard Warfarin After Mechanical Mitral Valve Replacement: A Randomized Trial. Ann Thorac Surg., S0003-4975 (23)00005-X. 2. Goldstone AB, et al. (2017). Mechanical or biologic prostheses for aortic-valve and mitral-valve replacement. N Engl J Med;377:1847-57. 3. Otto CM, et al. (2021). 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circ,143(5). doi: 10.1161/CIR.0000000000000932. 4. Vahanian A, et al. (2022). 2021 ESC/EACTS Guidelines for the management of valvular heart Disease. Eur Heart J.43(7):561-632.

On-X[®] Mitral Valve: Hemodynamics

The On-X Mitral Valve Demonstrates Optimal Performance in Large Landmark Study for Mechanical Mitral Valves

- The Prospective Randomized On-X Anticoagulation Clinical Trial (PROACT) Mitral Trial¹ is one of the largest studies ever conducted with mechanical mitral valves involving 401 patients (mean age 55 y/o) at 44 North American centers.
- PROACT Mitral represents the most contemporary evidence on performance and anticoagulation for any mechanical mitral valve.
- Due to its size and scope, a similar study is likely to never be repeated.

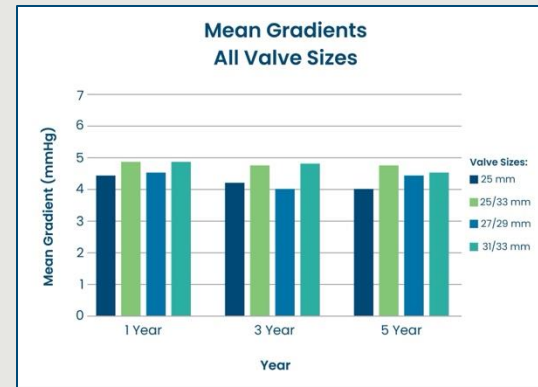
Figure 1



Echocardiographic data showed patients with the following EOAs across all On-X Mitral Valve sizes (Figure 1):

- 2.9 cm² at 1 year
- 3.4 cm² at 3 years
- 2.8 cm² at 5 years

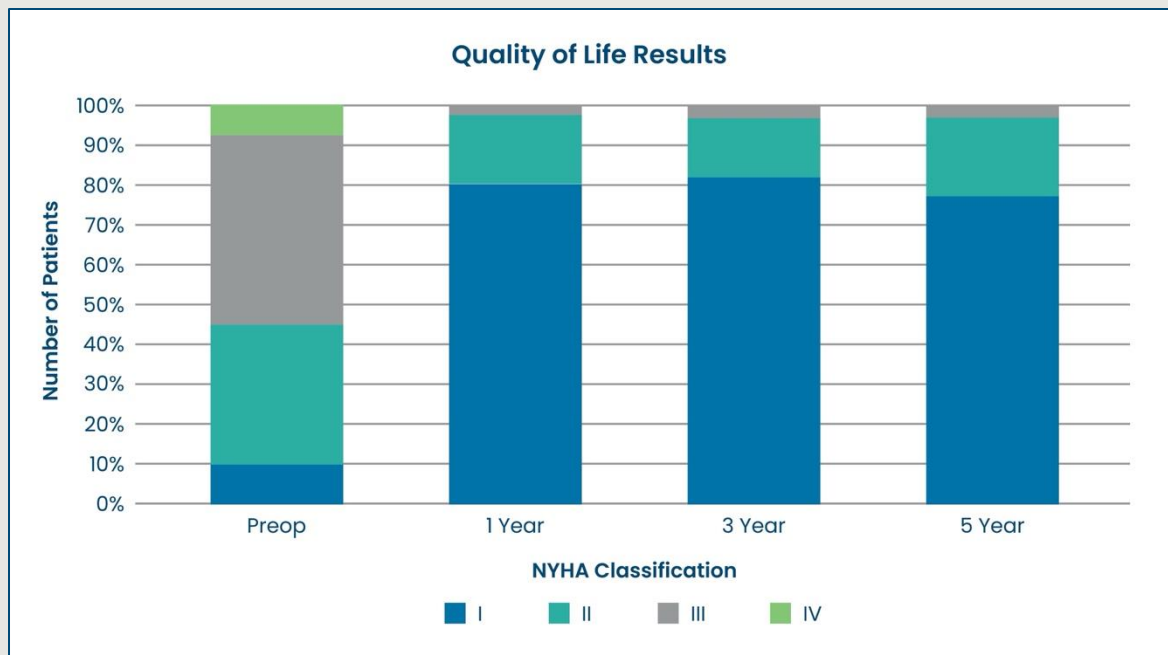
Figure 2



Patients had exceptional mean gradients below 5mmHg across all On-X Mitral Heart Valves sizes, sustained out to 5 years. (Figure 2)

On-X[®] Mitral Valve: Quality of Life

The On-X Mechanical Mitral Valve, which is engineered for exceptional clinical performance, now has the most robust body of evidence supporting its use as demonstrated by sustained quality of life improvements in PROACT Mitral.



On-X[®] Mitral Valve Configurations

Sewing Ring Type	Mitral Valve Image	Valve Sizes (mm): Catalog Number
Standard	 A 3D rendering of a standard On-X mitral valve. It features a light blue, textured sewing ring with a central black chord and a black frame.	23: ONXM-23 [†] 25: ONXM-25 27/29: ONXM-27/29 31/33: ONXM-31/33
Conform-X	 A 3D rendering of a Conform-X On-X mitral valve. It features a light blue, textured sewing ring with a central black chord and a black frame, similar to the standard version but with a slightly different shape.	23/33: ONXMC-25/33

On-X[®] Product Accessories & Portfolio

On-X® Product Accessories

On-X Instrument Kit – Aortic and Mitral¹

Description	Product Code
13 instruments total	ONXI3-CK

On-X Aortic Sizers

Description	Product Code
For valve size 19	ONXI3-19S
For valve size 21	ONXI3-21S
For valve size 23	ONXI3-23S
For valve size 25	ONXI3-25S
For valve size 27/29	ONXI3-27-29S

On-X Mitral Sizers

Description	Product Code
For valve sizes 23, 25 and 25/33	ONXI3-23-25S
For valve sizes 25/33, 27/29, and 31/33	ONXI3-27-33S

Note: The size of the On-X Mitral Valve with the Standard Sewing Ring corresponds to the size on the Mitral Sizer. The size of the On-X Mitral Valve with the Conform-X Sewing Ring depends on the size of the patient's anatomy and the Mitral Sizer for the 25, 27/29, or 31/33 may be applicable.

On-X Rotators

Description	Product Code
For valve size 19	ONXI2-19R
For valve size 21	ONXI2-21R
For valve size 23	ONXI2-23R
For valve sizes 25-33	ONXI2-25R
For mitral valve sizes 25-33 ¹	ONXI3-25MR

On-X Handle & Probe (universal)

Description	Product Code
Instrument Handle	ONXI2-H
Leaflet Probe	ONXI2-LP

On-X Sterilizable Tray

Description	Product Code
Tray Only - No Instruments	ONXI3-CT

On-X Aortic Sizers



On-X Mitral Sizers



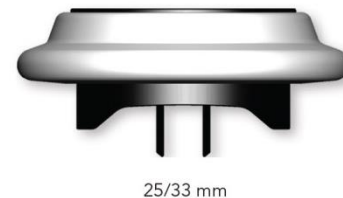
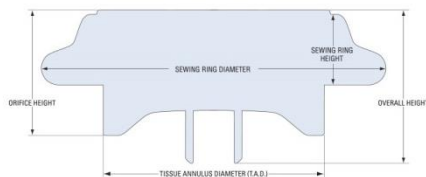
Rotators, Instrument Handle, and Leaflet Probe



On-X® Product Portfolio

On-X Valve Specifications

On-X Prosthetic Mitral Valve with Conform-X Sewing Ring¹



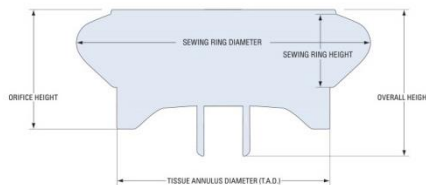
Valve Size	Product Code	Tissue Annulus Diameter (mm)	Internal Diameter (mm)	Sewing Ring Diameter ² (mm)	Overall Height (mm)	Orifice Height (mm)	Internal Orifice Area (cm ²)
25/33	ONXMC-25/33	25-33	23.4	39	17.8	14.2	4.11

1. All On-X Valve sewing rings are made from polytetrafluoroethylene (PTFE)
2. Sewing rings nominal dimensions

On-X® Product Portfolio

On-X Valve Specifications

On-X Prosthetic Mitral Valve with Standard Sewing Ring¹



23 mm and 25 mm



27/29 mm and 31/33 mm

Valve Size	Product Code	Tissue Annulus Diameter (mm)	Internal Diameter (mm)	Sewing Ring Diameter ² (mm)	Overall Height (mm)	Orifice Height (mm)	Internal Orifice Area (cm ²)
23	ONXM-23	23	21.4	31	16.1	13.1	3.44
25	ONXM-25	25	23.4	33	17.8	14.2	4.11
27/29	ONXM-27/29	27-29	23.4	34	17.8	14.2	4.11
31/33	ONXM-31/33	31-33	23.4	36	17.8	14.2	4.11

[†]Size 23 mitral valves are not available for sale in the United States.

1. All On-X Valve sewing rings are made from polytetrafluoroethylene (PTFE)

2. Sewing rings nominal dimensions

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