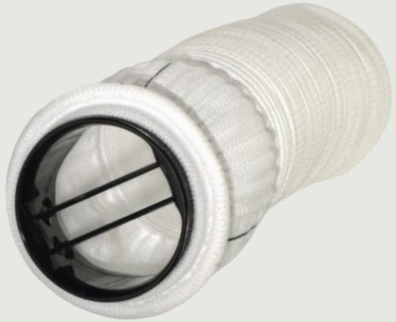
# On-X® Heart Valve Solutions Overview

**On-X®**
Aortic Heart Valve



**On-X®**
Ascending Aortic Prosthesis

**On-X®**
Mitral Heart Valve



ARTIVION™

# Pinnacle of Valve Material & Design



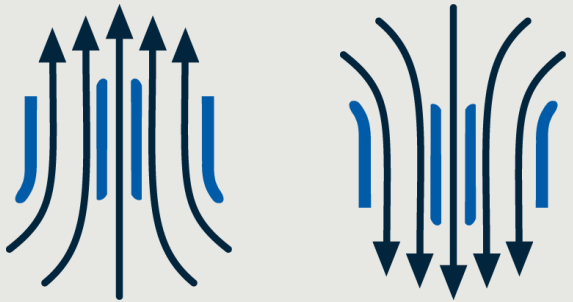
ARTIVION

# Better Laminar Flow

## On-X®
## Aortic and Mitral Valves

**90º Opening**

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



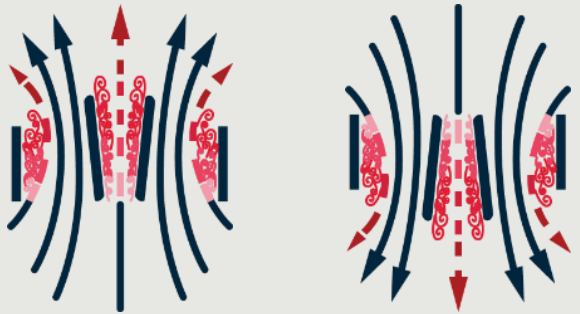
Aortic Mitral

VS

## All Other Bileaflet
## Aortic and Mitral Valves

**< 90º Opening**

All other bileaflet aortic and mitral valves have leaflets that can only open 78º to 85º.[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).

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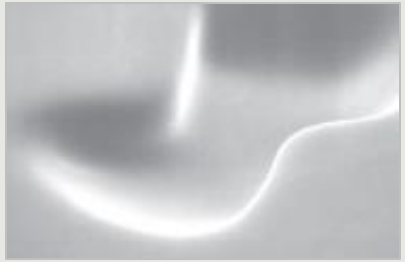
# Reduced Thrombogenicity

## On-X®
## Aortic and Mitral Valves

### Smoother Surface

On-X Aortic and Mitral Valves have a smoother surface[1] on the entire body and leaflets to reduce thrombogenicity.[2]



Smooth Pivot[2]

Pure Pyrolytic Carbon[2]

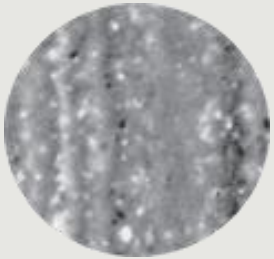
VS

## All Other Bileaflet
## Aortic and Mitral Valves

### Rougher Surface

All other bileaflet aortic and mitral valves have rougher surfaces[1] that are more thrombogenic.[2]

Rough Machined Pivot[2]



Silicon Alloyed Pyrolytic Carbon[2]



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.

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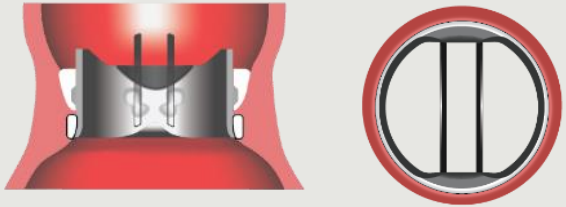
# Complete Annulus Support

## On-X®
## Aortic and Mitral Valves

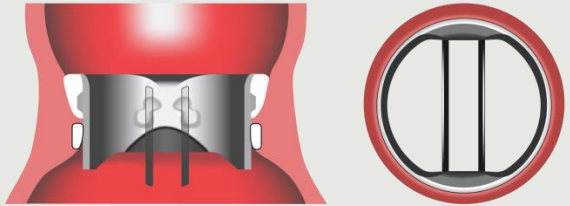
### Complete Annulus Support

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.

Aortic



Mitral



VS

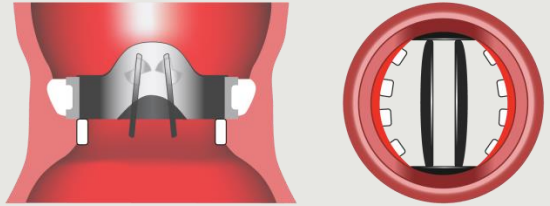
## All Other Bileaflet
## Aortic and Mitral Valves

### Incomplete Annulus Support

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

Aortic

Mitral





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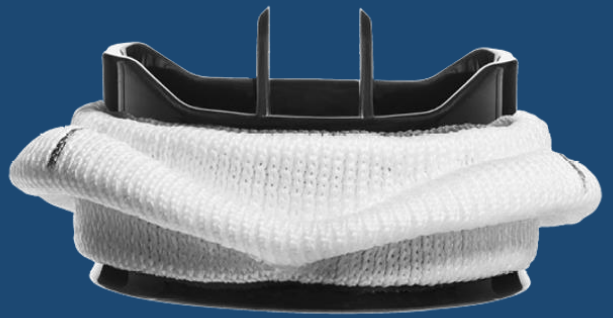
# On-X® Aortic Heart Valves





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# On-X®
# Aortic Heart Valve

# 87% LOWER BLEEDING RISK AT 5-YEARS[1]

On-X Aortic is the ONLY mechanical valve available with **87%** lower bleeding risk and **50%** Lower INR.[1]



1. Gerdisch MW, et al. Low-Dose Warfarin with a Novel Mechanical Aortic Valve: Interim Registry Results at 5-Year Follow-Up, J Thorac Cardiovasc Surg (2024), doi: https://doi.org/10.1016/j.jtcvs.2024.04.017

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# 50% Closer to a Normal INR[1]

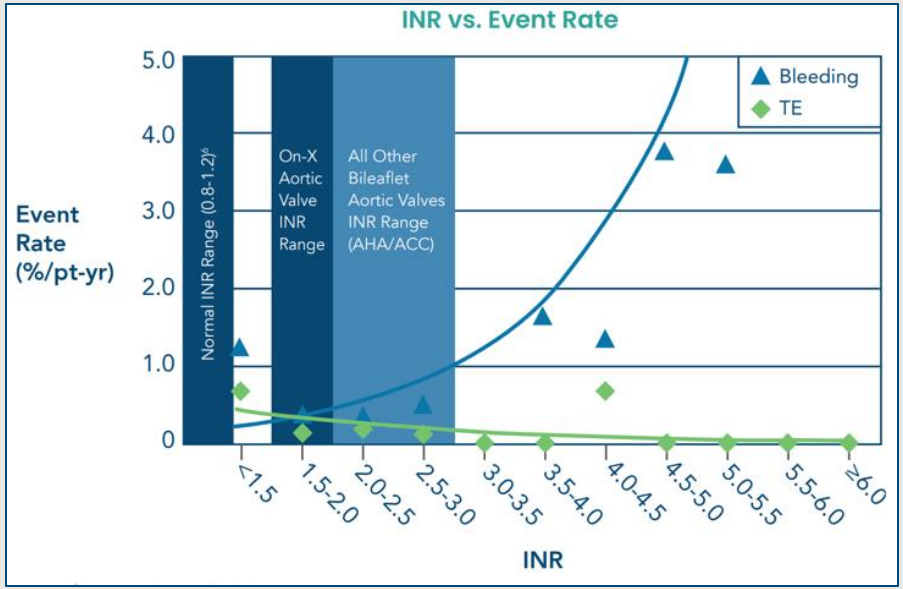
**P**rospective **R**andomized **O**n-X Valve **A**nticoagulation **C**linical **T**rial (PROACT) clinically proves the On-X Aortic Valve to be safe with 50% less anticoagulation than standard mechanical aortic valves, resulting in a **significant reduction in major bleeding** and **no increase in thromboembolism**.*[2,3] Patients with an On-X Aortic Valve can manage their INR at the low range of 1.5-2.0, while all other standard mechanical aortic valve anticoagulation should be managed at an INR of 2.0-3.0.[3]

## On-X Aortic Valve

The **only mechanical aortic valve approved for low INR (1.5–2.0)** by FDA, Health Canada, and CE Mark, based on the PROACT study data.

## 2020 ACC/AHA Guidelines

Directly support targeting an INR of 1.5-2.0 in patients with an On-X Aortic Valve and with no thromboembolic risk factors.




*Reduce INR after 3 months of standard therapy.[2]

1. Normal INR is considered 1.0. WHO Expert Committee on Biological Standardization, 33rd Report, World Health Organization, 1983. 2. On-X Prosthetic Heart Valve Instructions for Use, 010122 77 E (2020-12). 3. Puskas J, et. al. (2014). J Thorac Cardiovasc Surg, 147(4), 1201-11. 2. Otto CM, et al. (2021). Circulation, 143:e72–e227. https://doi.org/10.1161/CIR.0000000000000923.



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# 87% Lower Bleeding Risk

## On-X Aortic Heart Valve Post Approval Study

In a real-world setting, the On-X Aortic Valve remains safe at low INR of 1.5-2.0, reducing the risk of major bleeding by 87% with no increase in thromboembolism and no valve thrombosis at 5-years.[1]

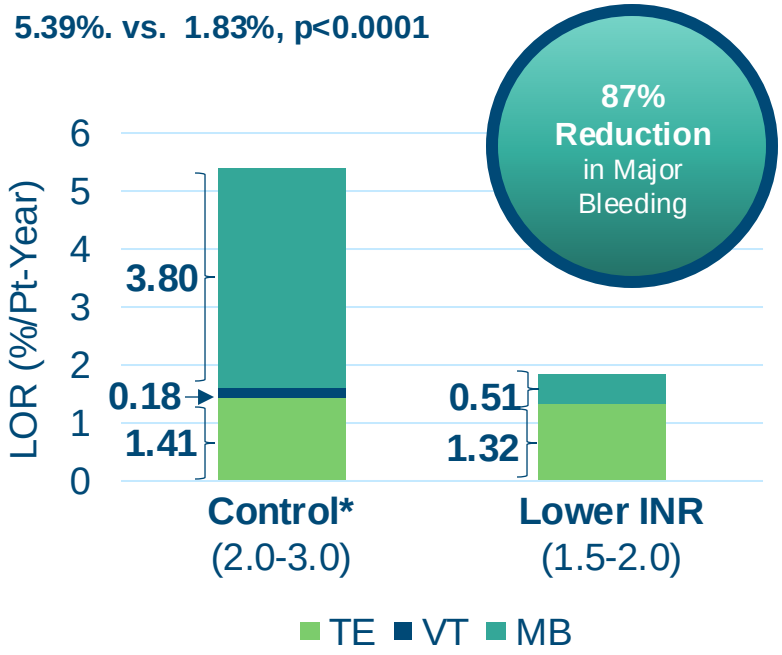
**229**
**Patients**

**53.2**
**Mean Age** (yrs)

### INR Monitoring Methods

Clinic
**83.8%**

Home
**16.2%**




1. Gerdisch MW, et al. Low-Dose Warfarin with a Novel Mechanical Aortic Valve: Interim Registry Results at 5-Year Follow-Up, J Thorac Cardiovasc Surg (2024), doi: https://doi.org/10.1016/j.jtcvs.2024.04.017. 2. Artivion data on file, weighted average of control groups from FDA Premarket Approval P000037 S030 and IDE trial G050208.



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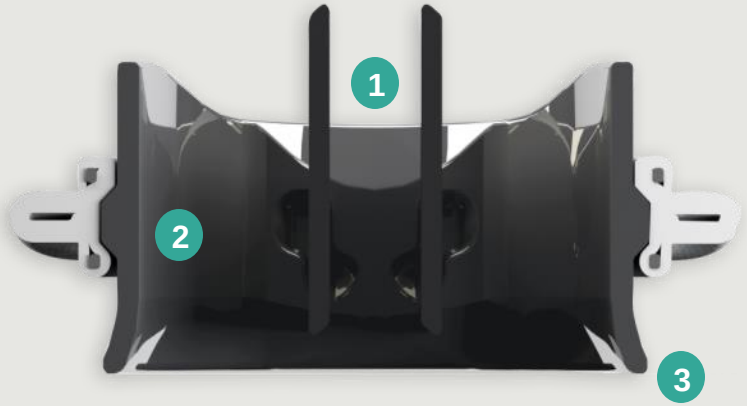
# Unique Material & Designed to Prevent Pannus




**Inlet Flare Designed to Prevent Pannus[1,2]**
**98.5% Freedom from Pannus Formation at 20-Years with the On-X Aortic Valve[1,3]**

**Valve Profile Protects Leaflets from Impingement[2] and Preserves Vortical[¥] Flow[1]**

## No Other Mechanical Valve Has:

1. **90° Leaflets:[2]** promotes laminar flow
2. **Pure Pyrolytic Carbon:** reduces thrombogenicity[2]
3. **Flared Inlet:** organizes flow; prevents pannus

¥ Vortical flow propels blood into the coronary arteries through the sinuses of Valsalva, maintains coronary flow reserve, and assists in the closure of the aortic valves.[1]

1. Gerdisch MW, et al. Progress in Cardiovascular Diseases. 2022:72;31-40. https://doi.org/10.1016/j.pcad.2022.06.001. 2. On-X Prosthetic Heart Valve Instructions for Use, 010122 77 E (2020-12). 3. Choi JW, et al. Thorac Cardiovasc Surg 2022;70(3):182-188. https://doi.org/10.1055/s-0041-1727152.



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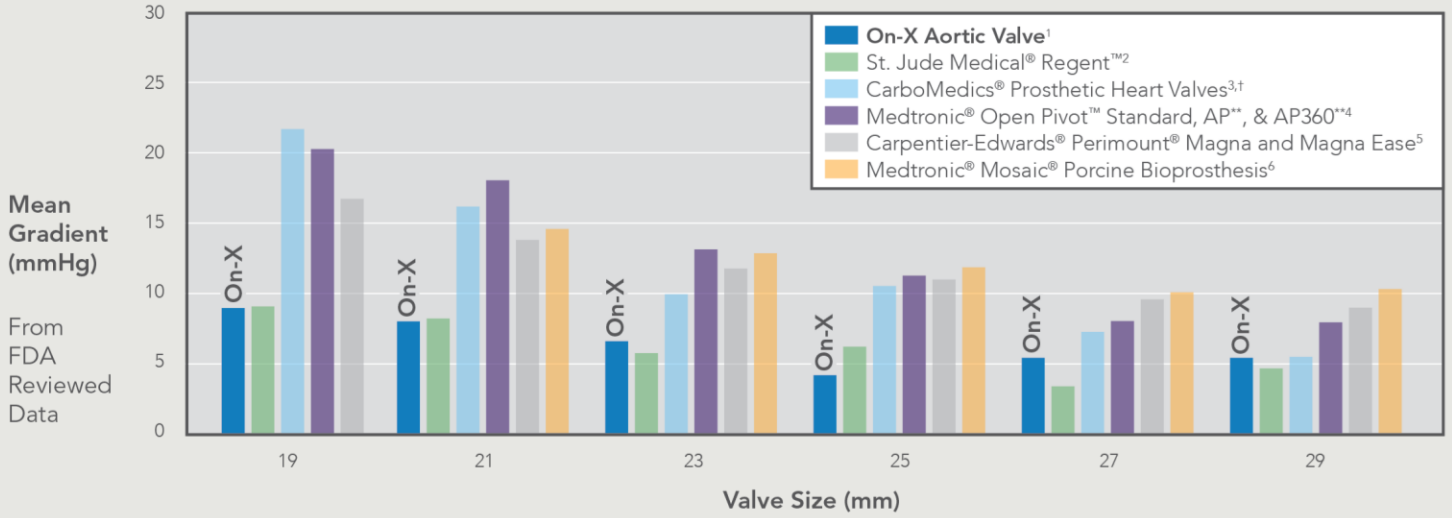
# Optimal Hemodynamics

The On-X Aortic Valve provides optimal mean gradients compared with other bileaflet and bioprosthetic aortic valves at ≥1 year.[1-6,†]

## Mean Gradients at ≥1 Year




** Medtronic Open Pivot AP and AP360 (formerly ATS): 16 = 19, 18 = 21, 20 = 23, 22 = 25, 24 = 27, 26 = 29

† Postoperative data. Note: Mean gradients for On-X Aortic Valve 27 and 29 were combined.


1. On-X Prosthetic Heart Valve Instructions for Use, 010122 77 C (2017-08). 2. St. Jude Medical Physician's Manual Mechanical Heart Valve, 681827-001A. 3. CarboMedics Prosthetic Heart Valve Instructions for Use, 226-07ED003L (1997-02). 4. Medtronic Open Pivot Heart Valve Instructions for Use, M951905A001 Rev. 1A (2013). 5. Edwards Life Sciences Carpentier-Edwards PERIMOUNT Magna Ease Pericardial Aortic Bioprosthesis Model 3300TFX Instructions for Use, 197682001 A (2009-04). 6. Medtronic Mosaic Porcine Bioprosthesis with Cinch Advanced Implant System Instructions for Use. 1220016001 Rev. 1B.

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# On-X® Aortic Valve Configurations

| Sewing Ring Type | Valve Image | Valve Sizes (mm): Catalog Number |
|---|---|---|
| **Standard** | | 19: ONXAE-19<br>21: ONXAE-21<br>23: ONXAE-23<br>25: ONXAE-25<br>27/29: ONXAE-27/29 |
| **Conform-X** | | 19: ONXACE-19<br>21: ONXACE-21<br>23: ONXACE-23<br>25: ONXACE-25<br>27/29: ONXACE-27/29 |
| **Anatomic** | | 19: ONXANE-19<br>21: ONXANE-21<br>23: ONXANE-23<br>25: ONXANE-25<br>27/29: ONXANE-27/29 |



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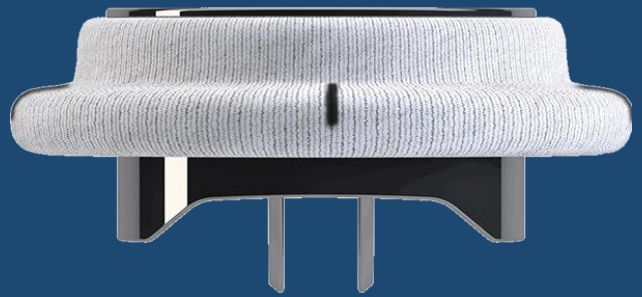
# On-X® Mitral Heart Valves





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# On-X®
# Mitral Heart Valve

# 4.6mmHG AVERAGE MEAN GRADIENT

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

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.



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# On-X® Mitral Valve: Redefining Size. Performance.

Standard

Conform-X

**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]**

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



1. On-X Prosthetic Heart Valve Instructions for Use, 010122 77 E (2020-12).
2. Magne et al., Impact of Prosthesis-Patient Mismatch on Survival After Mitral Valve Replacement. Circulation. 2007;115:1417-1425.

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# 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 Mitral[1].**

- The PROACT Mitral Study[1] 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

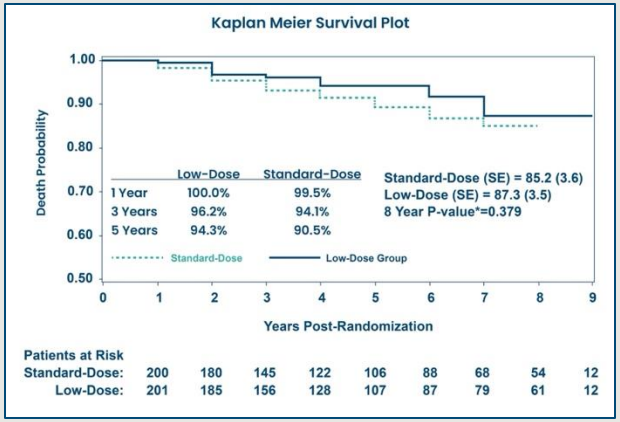
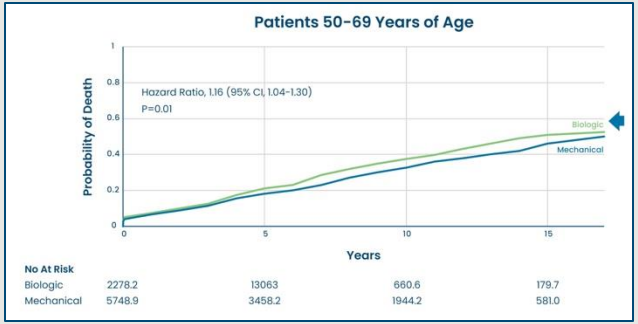



Figure 2




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.



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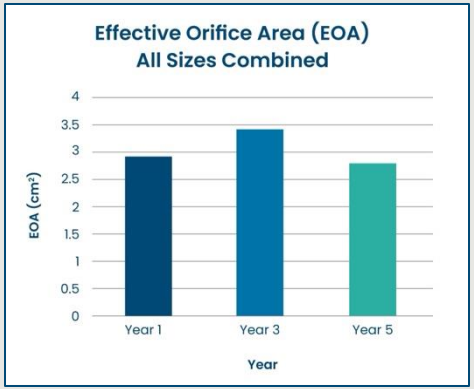
# On-X® Mitral Valve: Hemodynamics

## 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 Trial[1] 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.

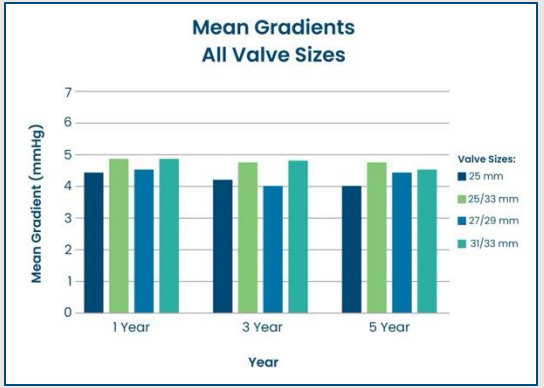
Figure 1




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

- 2.9 $cm^2$ at 1 year
- 3.4 $cm^2$ at 3 years
- 2.8 $cm^2$ 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)



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.

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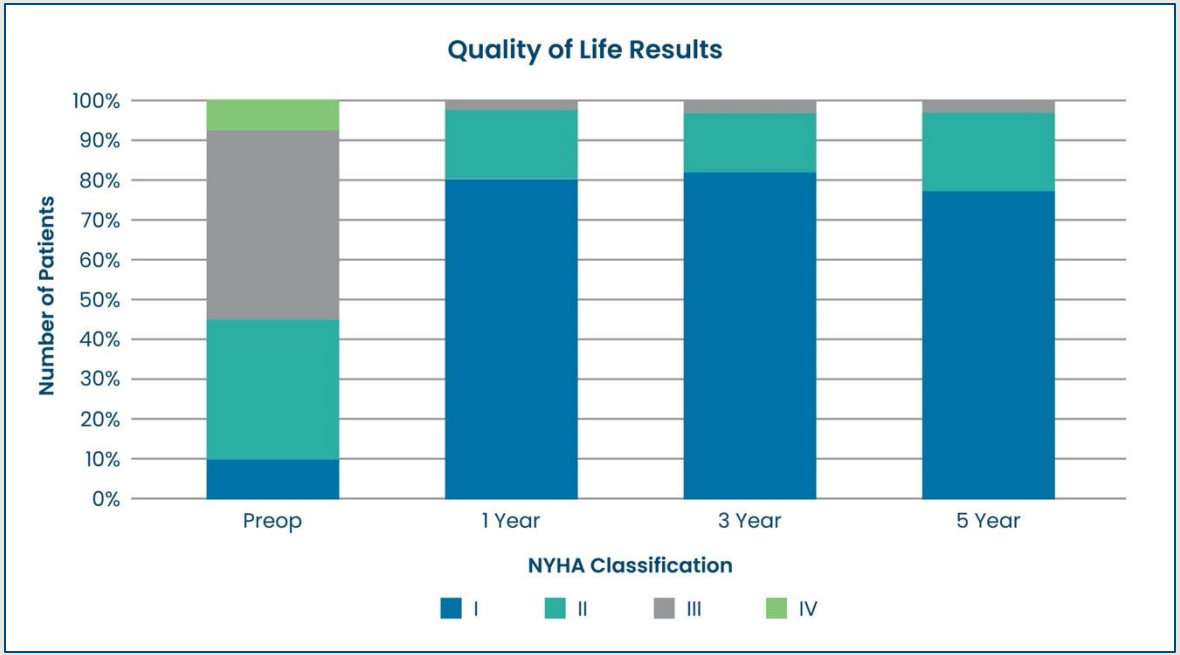
# On-X® Mitral Valve: Quality of Life

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.




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.



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# On-X® Mitral Valve Configurations

| Sewing Ring Type | Mitral Valve Image | Valve Sizes (mm): Catalog Number |
|---|---|---|
| **Standard** | | 23: ONXM-23†<br>25: ONXM-25<br>27/29: ONXM-27/29<br>31/33: ONXM-31/33 |
| **Conform-X** | | 23/33: ONXMC-25/33 |



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

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# On-X ® Ascending Aortic Prosthesis (AAP)

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# On-X® AAP Valved Conduit

**The Most Advanced Aortic Valved Conduit with:**

- On-X Aortic Valve with optimal hemodynamics[1]
- Valsalva Graft with geometry that mimics the sinus of Valsalva[2]

**Gelweave Valsalva Vascular Prosthesis** is a woven polyester prosthesis designed to mimic the geometry of the sinus of Valsalva. The graft is impregnated with an absorbable protein (modified mammalian gelatin) to eliminate pre-clotting of the graft in surgery.[2]

**On-X Ascending Aortic Prosthesis with Vascutek® Gelweave® Valsalva™** Graft is indicated for the replacement of a diseased, damaged, or malfunctioning native or prosthetic heart valve in the aortic position in cases that involve an ascending aortic aneurysm or other associated aortic disease.[2]



1. Keller EJ. et al., Interact CardioVasc Thorac Surg (2016) 23(3):416-423. 2. On-X Ascending Aortic Prosthesis Instructions for Use, AUS-LBL00189 B (2021-10).

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# On-X® AAP Valved Conduit

1. **90° leaflets**:[1] promotes laminar flow
2. **Pure pyrolytic carbon**: reduces thrombogenicity[2]
3. **Flared inlet**: prevents pannus; organizes flow
4. **Valsalva graft**: mimics the geometry of the sinus of Valsalva[1]
5. **Conform-X PTFE sewing ring**: for ease of suturing

**Optimal Hemodynamics:**

"…[In comparison to the On-X AAP,] no non-native aortic valve has been able to produce 3D, in vivo haemodynamics that so closely approach flow patterns observed in healthy volunteers."[3]
Dr. S. Chris Malaisrie, United States

1. On-X Ascending Aortic Prosthesis Instructions for Use, AUS-LBL00189 B (2021-10). 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. 3. Keller EJ. et al., Interact CardioVasc Thorac Surg (2016) 23(3):416-423.



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# On-X® Product Accessories & Portfolio



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# On-X® Product Accessories

## On-X Instrument Kit – Aortic and Mitral[1]

| 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

The On-X instrument kit consists of one of every instrument listed above, except for the ONXI3-25MR, which is available separately upon request. Grey Sizers can be ordered through your local Artivion representative.



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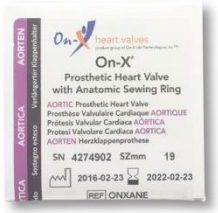
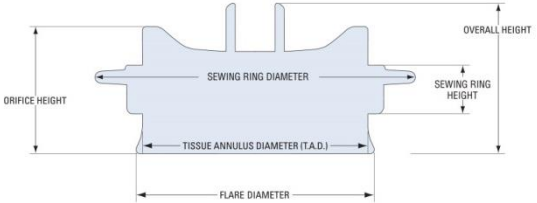
# On-X® Product Portfolio

## On-X Valve Specifications

### On-X Prosthetic Aortic Valve with Anatomic Sewing Ring[1]



19 mm to 27/29 mm

| Valve Size | Product Code | Tissue Annulus Diameter (mm) | Internal Diameter (mm) | Flare Diameter (mm) | Sewing Ring Diameter[2] (mm) | Overall Height (mm) | Orifice Height (mm) | Internal Orifice Area ($cm^2$) |
|---|---|---|---|---|---|---|---|---|
| 19 | ONXANE-19 | 19 | 17.4 | 20.1 | 27 | 13.3 | 10.8 | 2.28 |
| 21 | ONXANE-21 | 21 | 19.4 | 22.2 | 30 | 14.7 | 11.9 | 2.84 |
| 23 | ONXANE-23 | 23 | 21.4 | 24.3 | 33 | 16.1 | 13.1 | 3.44 |
| 25 | ONXANE-25 | 25 | 23.4 | 26.4 | 34 | 17.8 | 14.2 | 4.11 |
| 27/29 | ONXANE-27/29 | 27-29 | 23.4 | 26.4 | 36 | 17.8 | 14.2 | 4.11 |

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



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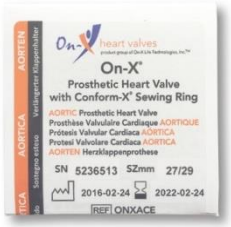
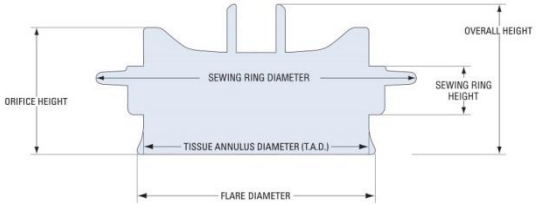
# On-X® Product Portfolio

## On-X Valve Specifications

### On-X Prosthetic Aortic Valve with Conform-X Sewing Ring[1]



19 mm to 25 mm

27/29 mm

| Valve Size | Product Code | Tissue Annulus Diameter (mm) | Internal Diameter (mm) | Flare Diameter (mm) | Sewing Ring Diameter[2] (mm) | Overall Height (mm) | Orifice Height (mm) | Internal Orifice Area ($cm^2$) |
|---|---|---|---|---|---|---|---|---|
| 19 | ONXACE-19 | 19 | 17.4 | 20.1 | 27 | 13.3 | 10.8 | 2.28 |
| 21 | ONXACE-21 | 21 | 19.4 | 22.2 | 30 | 14.7 | 11.9 | 2.84 |
| 23 | ONXACE-23 | 23 | 21.4 | 24.3 | 33 | 16.1 | 13.1 | 3.44 |
| 25 | ONXACE-25 | 25 | 23.4 | 26.4 | 34 | 17.8 | 14.2 | 4.11 |
| 27/29 | ONXACE-27/29 | 27-29 | 23.4 | 26.4 | 36 | 17.8 | 14.2 | 4.11 |

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



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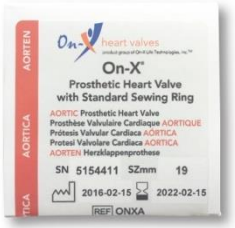
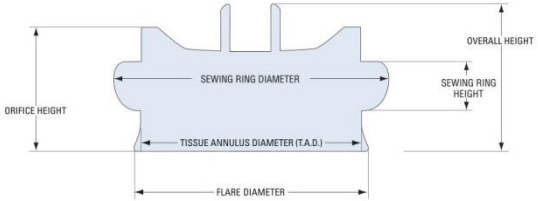
# On-X® Product Portfolio

## On-X Valve Specifications

### On-X Prosthetic Aortic Valve with Standard Sewing Ring[1]



19 mm to 25 mm

27/29 mm

| Valve Size | Product Code | Tissue Annulus Diameter (mm) | Internal Diameter (mm) | Flare Diameter (mm) | Sewing Ring Diameter[2] (mm) | Overall Height (mm) | Orifice Height (mm) | Internal Orifice Area ($cm^2$) |
|---|---|---|---|---|---|---|---|---|
| 19 | ONXAE-19 | 19 | 17.4 | 20.1 | 23 | 13.3 | 10.8 | 2.28 |
| 21 | ONXAE-21 | 21 | 19.4 | 22.2 | 26 | 14.7 | 11.9 | 2.84 |
| 23 | ONXAE-23 | 23 | 21.4 | 24.3 | 29 | 16.1 | 13.1 | 3.44 |
| 25 | ONXAE-25 | 25 | 23.4 | 26.4 | 32 | 17.8 | 14.2 | 4.11 |
| 27/29 | ONXAE-27/29 | 27-29 | 23.4 | 26.4 | 34 | 17.8 | 14.2 | 4.11 |

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



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# On-X® Product Portfolio

## On-X Valve Specifications

### On-X Ascending Aortic Prosthesis with the Vascutek® Gelweave® Valsalva™ Graft[1]

| Valve Size | Product Code | Valve Internal Diameter (mm) | Valve Orifice Area with Leaflets in Place ($cm^2$) | Sewing Ring Diameter[2] (mm) | Graft Diameter (mm) | Graft Length (cm) |
|---|---|---|---|---|---|---|
| 19 | ONXAAP-19 | 17.4 | 2.00 | 27 | 20 | 11 |
| 21 | ONXAAP-21 | 19.4 | 2.53 | 30 | 22 | 11 |
| 23 | ONXAAP-23 | 21.4 | 3.13 | 33 | 24 | 11 |
| 25 | ONXAAP-25 | 23.4 | 3.73 | 34 | 26 | 11 |
| 27/29 | ONXAAP-27/29 | 23.4 | 3.73 | 36 | 26 | 11 |

1. The Vascutek Gelweave Valsava Graft, is a product of Vascutek, a Terumo Company http//www.vascutek.com.
2. Sewing rings nominal dimensions



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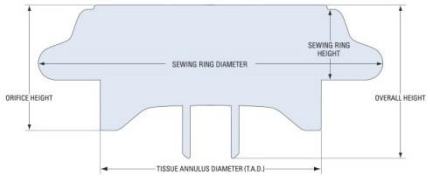
# On-X® Product Portfolio

## On-X Valve Specifications

### On-X Prosthetic Mitral Valve with Conform-X Sewing Ring[1]



25/33 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 ($cm^2$) |
|---|---|---|---|---|---|---|---|
| 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



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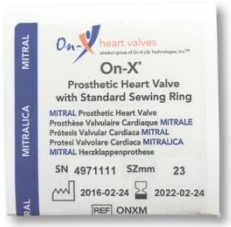
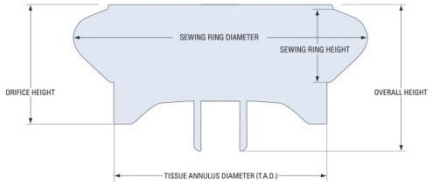
# On-X® Product Portfolio

## On-X Valve Specifications

### On-X Prosthetic Mitral Valve with Standard Sewing Ring[1]



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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