

On-X[®] Heart Valve Solutions Overview



On-X[®]
Aortic Heart Valve



On-X[®]
Ascending Aortic Prosthesis



On-X[®]
Mitral Heart Valve

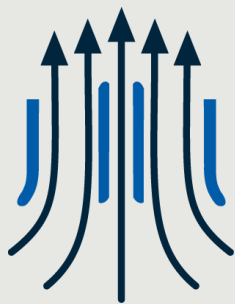
Pinnacle of Valve Material & Design

Better Laminar Flow

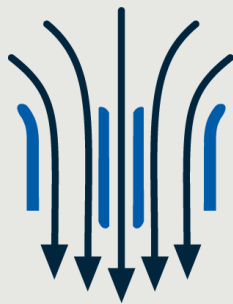
On-X[®] Aortic and Mitral Valves

90° Opening

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



Aortic



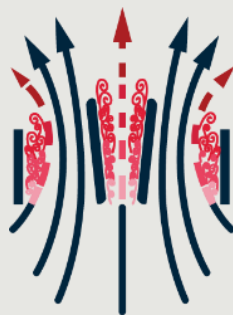
Mitral

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).

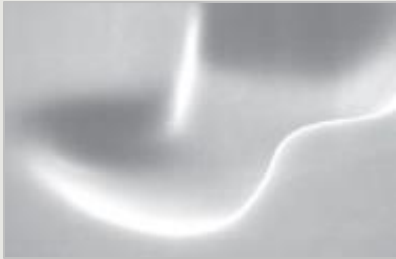
Reduced Thrombogenicity

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

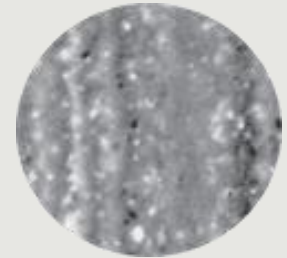
All Other Bileaflet Aortic and Mitral Valves

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.

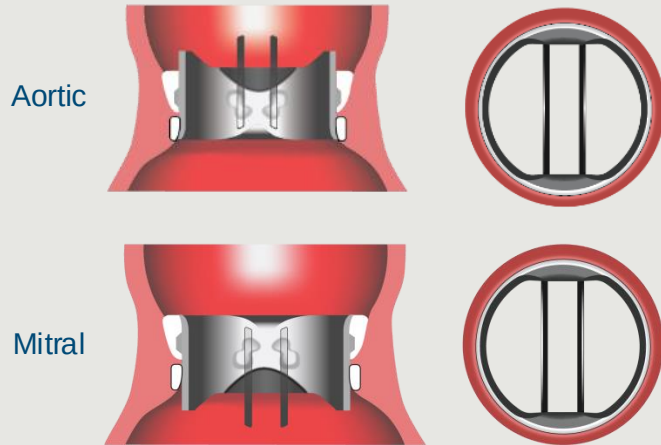
Complete Annulus Support

On-X®

Aortic and Mitral Valves

Complete Annulus Support

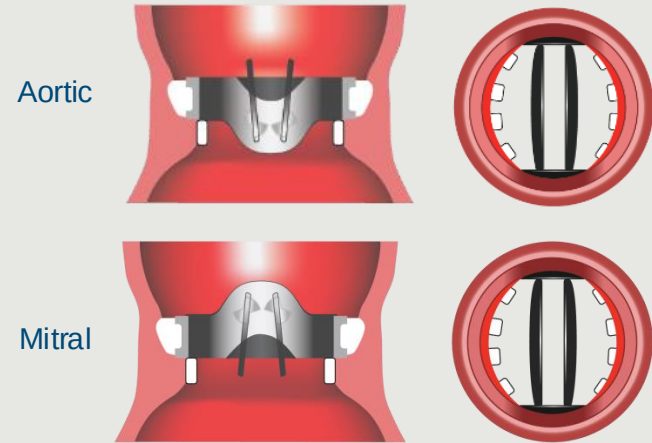
On-X Aortic and Mitral Valves have leaflet guards and a flared inlet designed to prevent pannus, encroachment of the subvalvular apparatus, and conceal pledgets.



All Other Bileaflet Aortic and Mitral Valves

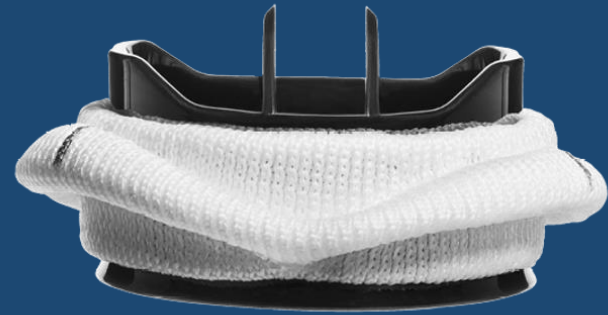
Incomplete Annulus Support

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



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On-X[®] Aortic Heart Valves



ARTIVION[®]



On-X[®] Aortic Heart Valve

87% LOWER BLEEDING RISK AT 5-YEARS¹

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

ARTIVION

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>

50% Closer to a Normal INR¹

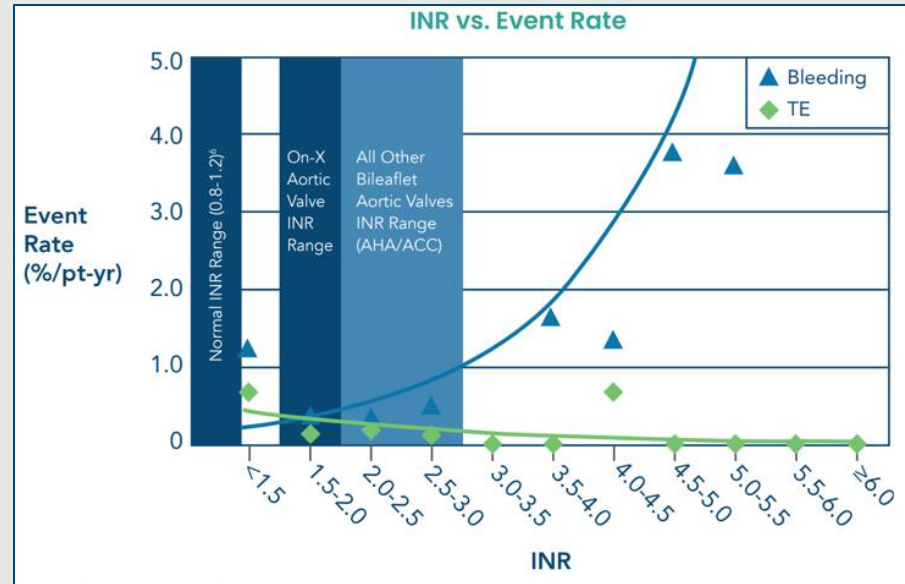
Prospective Randomized On-X Valve Anticoagulation Clinical Trial (PROACT) clinically proves the On-X Aortic Valve to be safe with 50% less anticoagulation than standard mechanical aortic valves, resulting in a **significant reduction in major bleeding** and **no increase in thromboembolism**.^{*2,3} 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



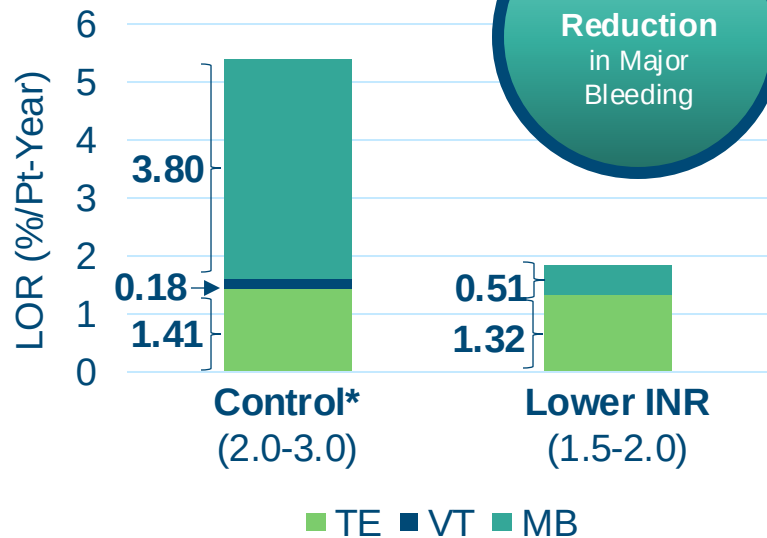
Clinic
83.8%



Home
16.2%

Composite Primary Endpoint

5.39%. vs. 1.83%, $p < 0.0001$



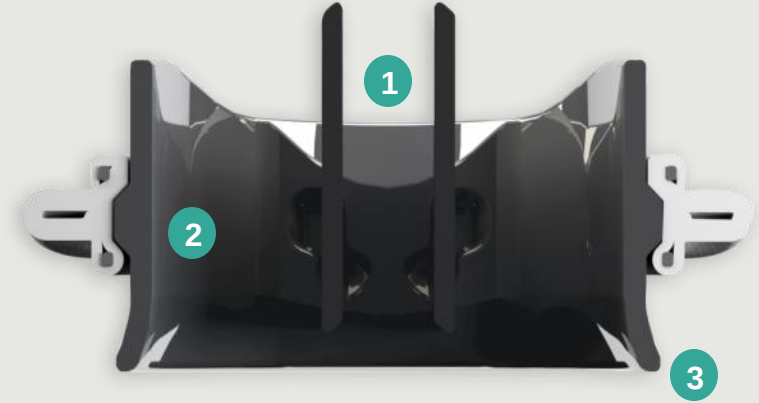
1. Gerdisch MW, et al. Low-Dose Warfarin with a Novel Mechanical Aortic Valve: Interim Registry Results at 5-Year Follow-Up, J Thorac Cardiovasc Surg (2024), doi: <https://doi.org/10.1016/j.jtcvs.2024.04.017>. 2. Artivion data on file, weighted average of control groups from FDA Premarket Approval P000037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

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
Impingement² and Preserves Vortical[¥] Flow¹**



No Other Mechanical Valve Has:

- 1 90° Leaflets:**² promotes laminar flow
- 2 Pure Pyrolytic Carbon:** reduces thrombogenicity²
- 3 Flared Inlet:** organizes flow; prevents pannus

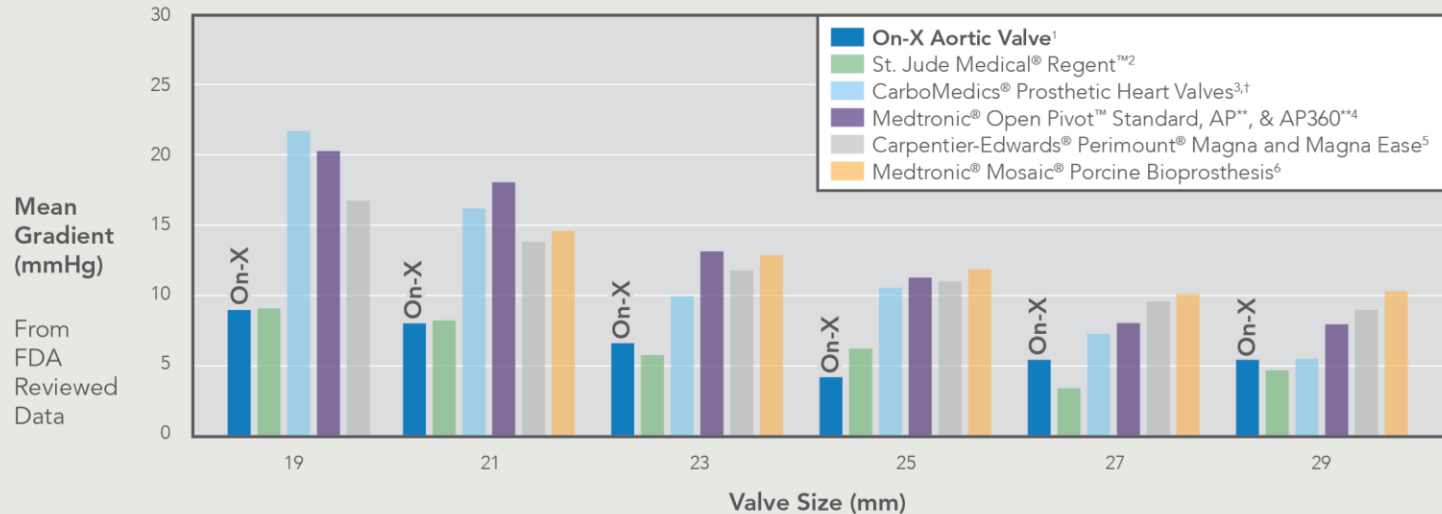
[¥] Vortical flow propels blood into the coronary arteries through the sinuses of Valsalva, maintains coronary flow reserve, and assists in the closure of the aortic valves.¹

1. Gerdtsch 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>.

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



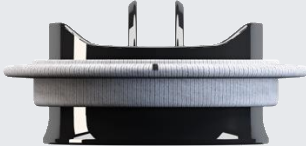
** Medtronic Open Pivot AP and AP360 (formerly ATS): 16 = 19, 18 = 21, 20 = 23, 22 = 25, 24 = 27, 26 = 29

† 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 21: ONXAE-21 23: ONXAE-23 25: ONXAE-25 27/29: ONXAE-27/29
Conform-X		19: ONXACE-19 21: ONXACE-21 23: ONXACE-23 25: ONXACE-25 27/29: ONXACE-27/29
Anatomic		19: ONXANE-19 21: ONXANE-21 23: ONXANE-23 25: ONXANE-25 27/29: ONXANE-27/29

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



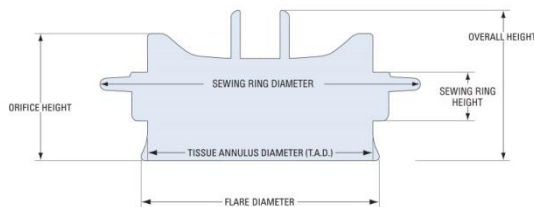
Rotators, Instrument Handle, and Leaflet Probe



On-X® Product Portfolio

On-X Valve Specifications

On-X Prosthetic Aortic Valve with Anatomic Sewing Ring¹



19 mm to 27/29 mm

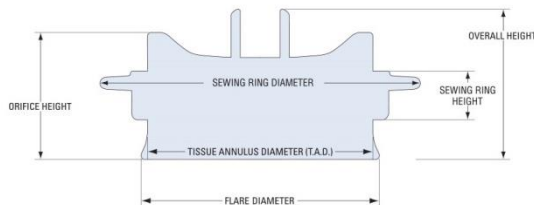
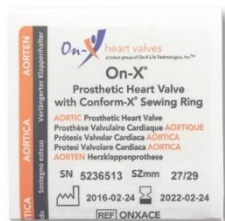
Valve Size	Product Code	Tissue Annulus Diameter (mm)	Internal Diameter (mm)	Flare Diameter (mm)	Sewing Ring Diameter ² (mm)	Overall Height (mm)	Orifice Height (mm)	Internal Orifice Area (cm ²)
19	ONXANE-19	19	17.4	20.1	27	13.3	10.8	2.28
21	ONXANE-21	21	19.4	22.2	30	14.7	11.9	2.84
23	ONXANE-23	23	21.4	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

On-X® Product Portfolio

On-X Valve Specifications

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



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

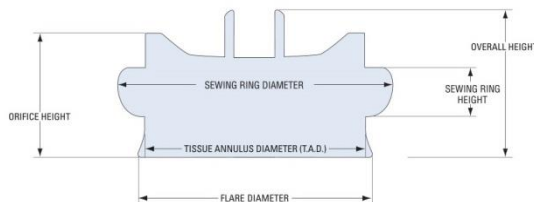
1. All On-X Valve sewing rings are made from polytetrafluoroethylene (PTFE)

2. Sewing rings nominal dimensions

On-X® Product Portfolio

On-X Valve Specifications

On-X Prosthetic Aortic Valve with Standard Sewing Ring¹



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

ARTIVION™

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