

Designed for life

Nature's Curves...
The first mechanical
aortic valve cuff that mimics
annular shape



On-X[®] Prosthetic Heart Valve with Anatomic Sewing Ring

- Matches the scalloped “crown-shaped” structure of the aortic annulus
- Helps prevent the flattening and distortion of the natural aortic annulus
- Provides a generous PTFE sewing ring that mimics nature’s shape
- Helps facilitate implantation of small aortic root valves
- May simplify implantation of double valves
- On-X valves are presently being studied in the only FDA approved trial for lowered INR or non-warfarin therapy

Product Specifications

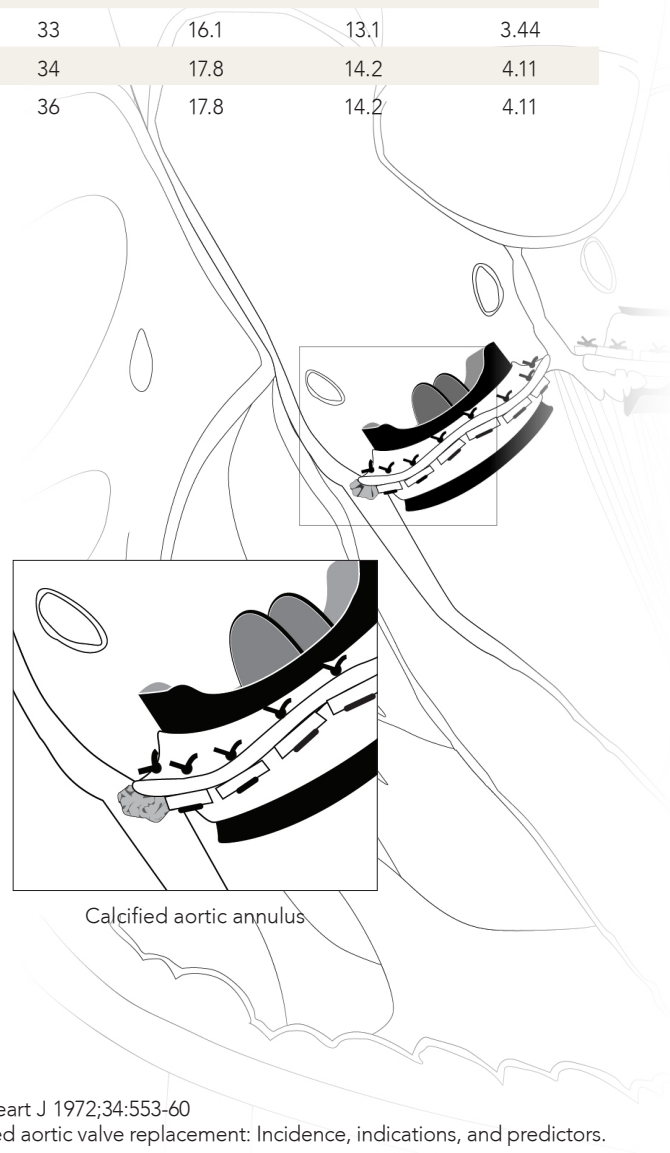
On-X Prosthetic Aortic Valve with Anatomic Sewing Ring "Patent pending"

Valve Size	Catalog Number	Tissue Annulus Diameter (mm)	Internal Diameter (mm)	Flare Diameter (mm)	Sewing Ring ¹ Diameter (mm)	Overall Height (mm)	Orifice Height (mm)	Orifice Area w/o Leaflets (cm ²)
19	ONXANE-19	19.0	17.4	20.1	27	13.3	10.8	2.28
21	ONXANE-21	21.0	19.4	22.2	30	14.7	11.9	2.84
23	ONXANE-23	23.0	21.4	24.3	33	16.1	13.1	3.44
25	ONXANE-25	25.0	23.4	26.4	34	17.8	14.2	4.11
27/29	ONXANE-27/29	27.0-29.0	23.4	26.4	36	17.8	14.2	4.11

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

Less annular distortion from a more correct anatomical shape may provide an additional benefit—

- Conduction disturbances are common after aortic valve replacement—as much as 26%.¹
- Dawkins and associates state, "The intimate relationship between the aortic valve and conducting tissue has led to the suggestion that direct trauma at the time of surgery might be involved, occurring as a consequence of injury from sutures, pressure from residual calcific material, or impingement of the prosthetic valvular seat on conducting tissue."²
- Erasmi and associates state, "The more the aortic valve is fixed with noncompliant prosthetic material, the more the native root dynamics are impaired."³
- Permanent pacemaker insertion has been reported to be from 1-9% after aortic valve surgery.³



Patent Pending

REFERENCES:

1. Follath F, Ginks WR. Changes in the QRS complex after aortic valve replacement. *B Heart J* 1972;34:553-60
2. Dawkins S, Hobson AR, Kalra PR, et al. Permanent pacemaker implantation after isolated aortic valve replacement: Incidence, indications, and predictors. *Ann Thorac Surg* 2008;85:108-12 doi:10.1016/j.athoracsur.2007.08.024
3. Erasmi A, Sievers H-H, Scharfshwerdt M, et al. In vitro hydrodynamics, cusp-bending deformation, and root distensibility for different types of aortic valve-sparing operations: Remodeling, sinus prosthesis, and reimplantation. *J Thorac Cardiovasc Surg* 2005;130:1044-49

Not all On-X valve models are available in all markets.

CAUTION: Federal law restricts this device to sale by or on the order of a physician. Refer to the Instructions for Use that accompany each valve for indications, contraindications, warnings, precautions and possible complications. CAUTION: Investigational use of this device in the Prospective Randomized On-X Valve Anticoagulation Trial (PROACT) is limited by federal law to investigational sites. For further information, visit www.onxlti.com

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