



ISO 9001 / ISO 13485 / ISO 14001 / OHSAS 18001 / CE Certified / WHO GMP Compliant Co / US FDA Establishment Regn No : 3005141524

# CARDIOTHORACIC & VASCULAR SURGERY



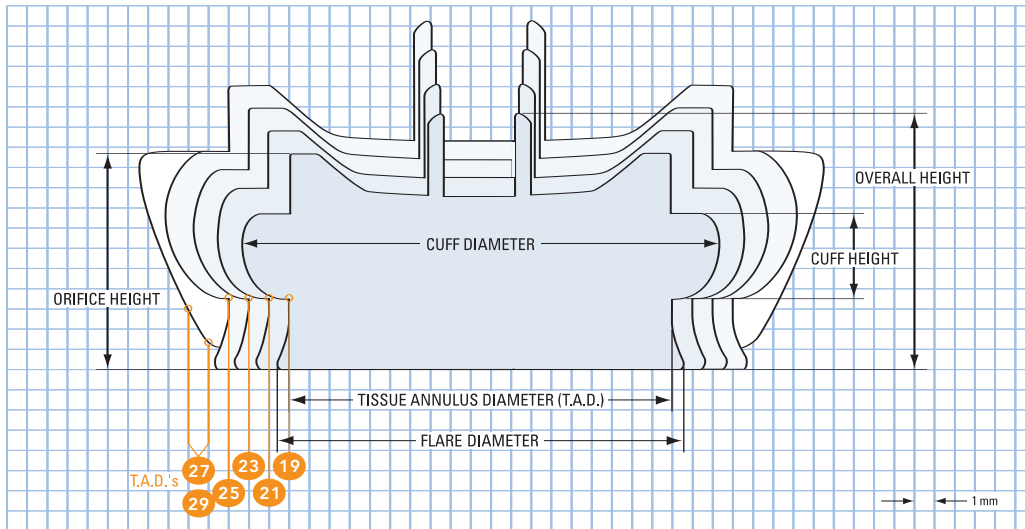
**LIFELINE SYSTEMS**

PRIVATE LIMITED

Improving patient care worldwide is our concern

# ON-X Valve Specifications

## Aortic On-X Valve

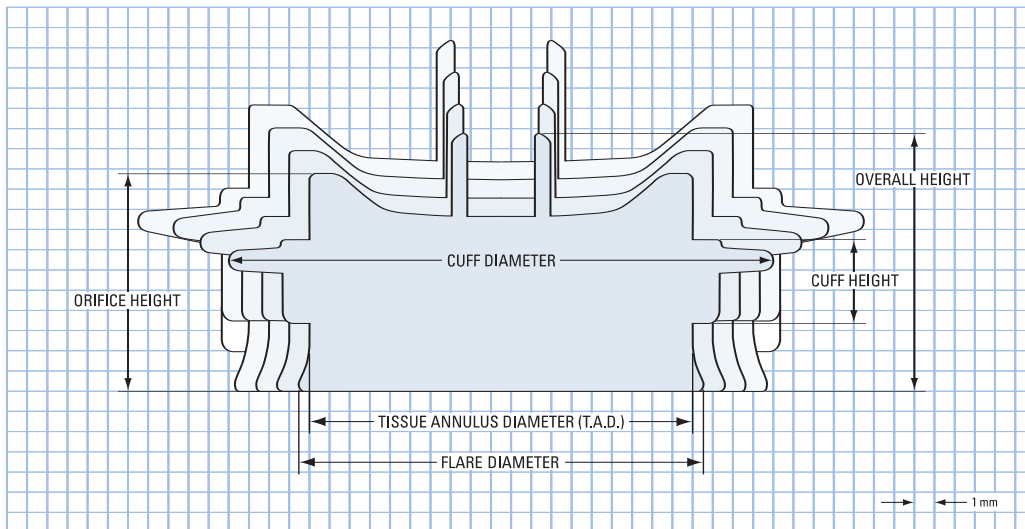


19 mm to 25 mm  
Supra-annular Cuff



27/29 mm  
Intra-annular Cuff

## Aortic On-X Valve with Conform-X Sewing Cuff



19 mm to 25 mm  
Supra-annular Cuff

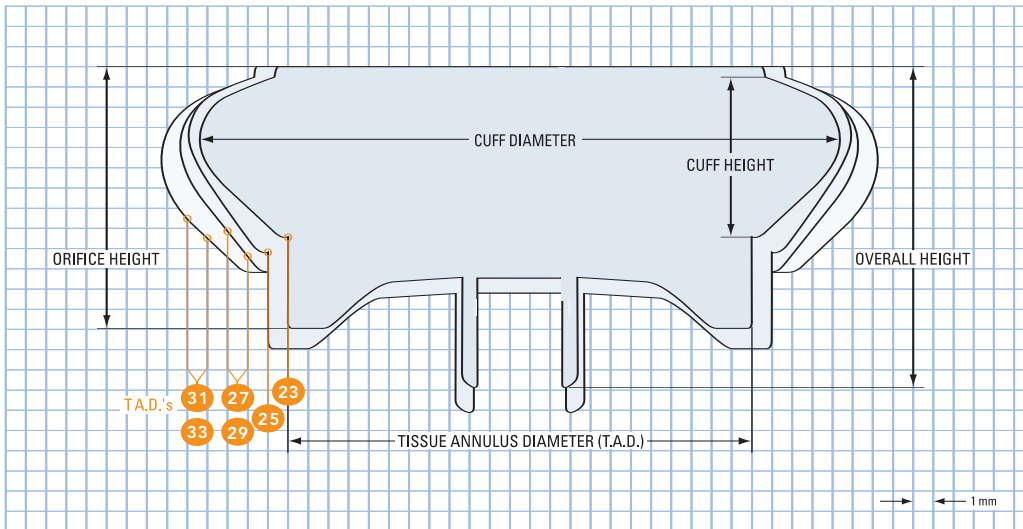


27/29 mm  
Supra-annular Cuff

Valve Size	Catalog Number	Tissue Annulus Diameter (mm)	Internal Diameter (mm)	Flare Diameter (mm)	Sewing Cuff Diameter (mm)	Overall Height (mm)	Orifice Height (mm)	Sewing Cuff Height (mm)	Orifice Area w/ Leaflets in Place (cm <sup>2</sup> )	Orifice Area w/o Leaflets (cm <sup>2</sup> )
<b>Aortic On-X Valve<sup>1</sup></b>										
19	ONXA-19	19.0	17.4	20.1	23.6	12.7	10.8	4.3	2.00	2.22
21	ONXA-21	21.0	19.4	22.2	26.0	14.2	11.9	5.6	2.53	2.79
23	ONXA-23	23.0	21.4	24.3	28.4	15.8	13.1	6.5	3.13	3.42
25	ONXA-25	25.0	23.4	26.4	31.4	17.4	14.2	7.4	3.73	4.09
27/29	ONXA-27/29	27.0-29.0	23.4	26.4	34.0	17.4	14.2	9.9	3.73	4.09
<b>Aortic On-X Valve with Conform-X Sewing Cuff<sup>1</sup></b>										
19	ONXAC-19	19.0	17.4	20.1	27.0	12.7	10.8	4.4	2.00	2.22
21	ONXAC-21	21.0	19.4	22.2	29.8	14.2	11.9	5.3	2.53	2.79
23	ONXAC-23	23.0	21.4	24.3	32.5	15.8	13.1	6.2	3.13	3.42
25	ONXAC-25	25.0	23.4	26.4	36.0	17.4	14.2	7.1	3.73	4.09
27/29	ONXAC-27/29	27.0-29.0	23.4	26.4	36.0	17.4	14.2	9.6	3.73	4.09

# ON-X Valve Specifications

## Mitral On-X Valve

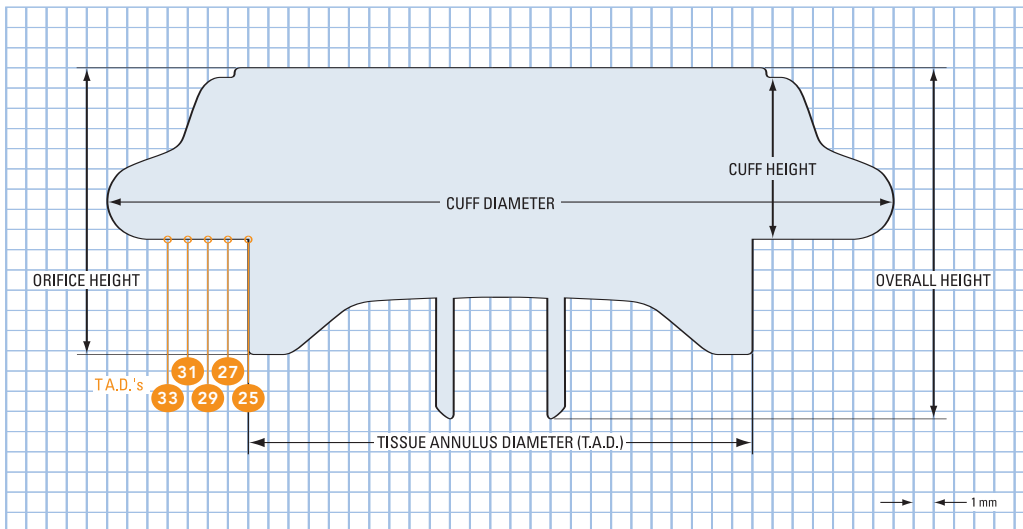


23<sup>2</sup> mm to 25 mm  
Supra-annular Cuff



27/29 mm and 31/33 mm  
Supra-annular Cuff

## Mitral On-X Valve with Conform-X Sewing Cuff



25/33 mm  
Supra-annular Cuff

Valve Size	Catalog Number	Tissue Annulus Diameter (mm)	Internal Diameter (mm)	Sewing Cuff Diameter (mm)	Overall Height (mm)	Orifice Height (mm)	Sewing Cuff Height (mm)	Orifice Area w/ Leaflets in Place (cm <sup>2</sup> )	Orifice Area w/o Leaflets (cm <sup>2</sup> )
<b>Mitral On-X Valve<sup>1</sup></b>									
23	ONXM-23 <sup>2</sup>	23.0	21.4	31.0	15.8	13.1	7.9	3.13	3.42
25	ONXM-25	25.0	23.4	33.0	17.4	14.2	8.8	3.73	4.09
27/29	ONXM-27/29	27.0-29.0	23.4	34.0	17.4	14.2	9.8	3.73	4.09
31/33	ONXM-31/33	31.0-33.0	23.4	36.0	17.4	14.2	9.8	3.73	4.09
<b>Mitral On-X Valve with Conform-X Sewing Cuff<sup>1</sup></b>									
25/33	ONXMC-25/33	25.0-33.0	23.4	39.0	17.4	14.2	8.8	3.73	4.09

1. All On-X and Conform-X cuffs are made of polytetrafluoroethylene (PTFE).  
2. Not available in the USA.

## ON-X Valve Instruments



### PRODUCT/SIZE

### CATALOG NO.

#### On-X Combination Instrument Kit - Aortic & Mitral

without Sterilizable Tray <sup>5</sup>	ONXI2-CK <sup>3</sup>
with Sterilizable Tray	ONXI2-CKT <sup>3</sup>

#### On-X Aortic Sizers – for all aortic valve configurations

for valve size 19	ONXI2-19S
for valve size 21	ONXI2-21S
for valve size 23	ONXI2-23S
for valve size 25	ONXI2-25S <sup>4</sup>
for valve size 27/29	ONXI2-27-29S

#### On-X Mitral Sizers

for valve sizes 23 and 25 and 25/33	ONXI2-23-25S
for valve sizes 27/29 and 31/33	ONXI2-27-33S <sup>4</sup>

#### On-X Rotators

for valve size 19	ONXI2-19R
for valve size 21	ONXI2-21R
for valve size 23	ONXI2-23R
for valve size 25 thru 33	ONXI2-25R

#### On-X Handle & Probe

Instrument Handle - All sizes	ONXI2-H
Leaflet Probe - All sizes	ONXI2-LP

#### On-X Combination Sterilizable Tray - Aortic & Mitral

Tray Only - No Instruments	ONXI2-CT
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- The Combination Instrument Kit contains instruments for both aortic and mitral procedures.
- In the original "Basic" instrument set, these sizers were universally used for both aortic and mitral applications. Accordingly, the cylindrical end of the 25 aortic sizer, and the 27-33 sizer, can be used for both aortic and mitral applications.
- The On-X Combination Instrument Kit consists of one each of the instruments shown on this page.

## On-X aortic and mitral valves are FDA approved.

**CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a physician. **INDICATIONS FOR USE:** The On-X<sup>®</sup> Prosthetic Heart Valve is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic heart valves in the aortic and mitral positions. **CONTRAINDICATIONS:** The On-X Prosthetic Heart Valve is contraindicated for patients unable to tolerate anticoagulation therapy. **WARNINGS AND PRECAUTIONS:** 1. FOR SINGLE USE ONLY. 2. DO NOT use the On-X Prosthetic Heart Valve if: the prosthesis has been dropped, damaged, or mishandled in any way; the tamper evident seal is broken; the serial number tag does not match the container label; or the expiration date has elapsed. 3. DO NOT re-sterilize any On-X Prosthetic Heart Valve once it is removed from its plastic container. 4. DO NOT re-sterilize more than 3 times. 5. DO NOT re-sterilize with any method other than steam sterilization, with the identified re-sterilization parameters. Note: Gamma radiation is known to damage the sewing ring. 6. DO NOT pass a catheter, surgical instrument, or transvenous pacing lead through the prosthesis as this may cause valvular insufficiency, leaflet damage, leaflet dislodgment, and/or catheter/instrument/lead entrapment. 7. Handle the prosthesis with only MCRI<sup>®</sup> On-X Prosthetic Heart Valve Instruments. Only MCRI On-X Prosthetic Heart Valve Sizers should be used during the selection of the valve size; other sizers may result in improper valve selection. 8. Avoid damaging the prosthesis through the application of excessive force to the valve orifice or leaflets. 9. Avoid contacting the carbon surfaces of the valve with gloved fingers or any metallic or abrasive instruments as they may cause damage to the valve surface not seen with the unaided eye that may lead to accelerated valve structural dysfunction, leaflet escape, or serve as a nidus for thrombus formation. **POTENTIAL ADVERSE EVENTS:** Adverse events potentially associated with the use of prosthetic heart valves (in alphabetical order) include, but are not limited to: angina, cardiac arrhythmia, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, myocardial infarction, prosthesis leaflet entrapment (impingement), prosthesis non-structural dysfunction, prosthesis pannus, prosthesis perivalvular leak, prosthesis regurgitation, prosthesis structural dysfunction, prosthesis thrombosis, thromboembolism and stroke. It is possible that these complications could lead to: reoperation, explantation, permanent disability and death.

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