ON-X® PROSTHETIC HEART VALVE, MODEL ONXA
Instructions for Use

English

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Instructions for Use

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

1. DEVICE DESCRIPTION

The On-X® Prosthetic Heart Valve (Figure 1) is a bileaflet mechanical heart valve, which consists of an orifice housing two leaflets. The orifice inflow area has a flared inlet designed to reduce flow turbulence, and the outflow rim consists of leaflet guards designed to protect the leaflets while in the closed position. The leaflets rotate around tabs located within the inner circumference of the orifice ring. In the closed position, the each leaflet forms a nominal angle of 40° relative to the plane of the orifice. In the open position, the plane of each leaflet forms a nominal angle of 90° relative to the plane of the orifice. The leaflets have a travel arc of 50° to the closed position.

The orifice is composed of graphite substrate coated with On-X® Carbon, a pure unalloyed form of pyrolytic carbon. The leaflets consist of On-X® Carbon deposited on a graphite substrate, which is impregnated with 10 weight% tungsten to provide radiopacity.

The sewing cuff is constructed of polytetrafluoroethylene (PTFE) fabric mounted on the orifice using titanium retaining rings and 5-0 suture material. This form of sewing cuff attachment to the orifice allows for rotation of the sewing cuff *in situ* during implantation. Orientation reference marks are provided on the sewing ring for valve orientation.

The On-X® Prosthetic Heart Valve is available in aortic sizes 19, 21, 23, 25, and 27/29 mm. Valve sizes 19 mm through 25 mm are designed for supra-annular implantation, while the valve size 27/29 mm is designed for intra-annular implantation.

2. INDICATIONS FOR USE

The On-X® Prosthetic Heart Valve is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic heart valves in the aortic position.

3. CONTRAINDICATIONS

The On-X® Prosthetic Heart Valve is contraindicated for patients unable to tolerate anticoagulation therapy.

4. WARNINGS AND PRECAUTIONS

4.1 Warnings

FOR SINGLE USE ONLY.

DO NOT use the On-X® Prosthetic Heart Valve if:

- the prosthesis has been dropped, damaged, or mishandled in any way;
- the expiration date has elapsed;
- the tamper evident seal is broken;
- the serial number tag does not match the container label.

DO NOT resterilize any On-X® Prosthetic Heart Valve:

- once it is removed from its plastic container;
- more than 3 times - resterilization of a valve which has passed the sterility expiration date is permitted, up to this limit, only if the valve has remained in the original unopened container and undamaged;
- with any method other than steam sterilization, with the identified resterilization parameters. Note: Gamma radiation is known to damage the sewing ring.

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.

4.2 Precautions

Handle the prosthesis with only MCRI™ 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.

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.

Avoid damaging the prosthesis through the application of excessive force to the valve orifice or leaflets.

5. ADVERSE EVENTS

A total of 184 aortic On-X® Prosthetic Heart Valves were implanted in 184 patients at 11 centers. The mean follow-up was 2.2 years (range of 0 to 4.0 years) with a total of 411.8 patient-years.

A total of 7 deaths occurred during the study and 2 of these were characterized as valve-related. The causes of the valve-related deaths were early thromboembolism (1 patient) and sudden, unexplained death (1 patient).

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5.1 Observed Adverse Events

Adverse events were reported in the clinical study as shown in the following table.

Table 1: Observed Adverse Event Rates[1]

All patients implanted, N = 184, Cumulative follow-up = 411.8 patient-years

Complication	Early Events		Late Events[2]		Freedom from Event[3], % [SE]	
	n	% (n/N)[4]	n	%/pt-yr	1Year Postoperative (n=138)	3 Year Postoperative (n=37)
Mortality (all)	4	2.2%	3	0.7%	97.8% [1.1]	96.0% [1.5]
Mortality (valve-related)	1	0.5%	1	0.2%	99.4% [0.5]	98.8% [0.9]
Endocarditis	0	0.0%	2	0.5%	99.4% [0.6]	98.9% [0.8]
Explant	1	0.5%	2	0.5%	98.4% [0.9]	97.8% [1.1]
Hemolysis[5]	0	0.0%	0	0.0%	100.0% [0]	100.0%[0]
Hemorrhage[6] (all)	1	0.5%	3	0.7%	99.4% [0.5]	97.3% [1.4]
Hemorrhage (major)	1	0.5%	1	0.2%	100.0% [0]	99.1% [0.9]
Perivalvular Leak (all)	4	2.2%	3	0.7%	96.7% [1.3]	96.7% [1.3]
Perivalvular Leak (major)	1	0.5%	0	0.0%	100.0% [0]	100.0% [0]
Nonstructural Valve Dysfunction	0	0.0%	0	0.0%	100.0% [0]	100.0% [0]
Reoperation (valve-related)	2	1.1%	3	0.7%	97.8% [1.1]	97.2% [1.2]
Structural Valve Dysfunction	0	0.0%	0	0.0%	100.0% [0]	100.0% [0]
Thromboembolism	1	0.5%	7	1.7%	97.8% [1.1]	93.9% [2.5]
Thrombosis	0	0.0%	0	0.0%	100.0% [0]	100.0% [0]

Notes:

1. Data does not include results from double valve replacement.
2. Late events calculated as linearized rates based on total patient-years.
3. Freedom from event was calculated based on the method of Kaplan-Meier. SE = Standard Error.
4. n = number of patients in each category; N = total number of study patients.
5. Blood studies conducted at a core laboratory established that the valve creates a low level of fully compensated hemolysis typified by an increase in SLDH with a mean within normal range, a decrease in haptoglobin to below normal in 69% AVR patients at 1-year, and all other analytes within normal range.
6. The anticoagulant agents used were reported. The target International Normalized Ratio was 2.5 to 3.5.

5.2 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 nonstructural dysfunction
- prosthesis pannus
- prosthesis perivalvular leak
- prosthesis regurgitation
- prosthesis structural dysfunction
- prosthesis thrombosis

- stroke
- thromboembolism

It is possible that these complications could lead to:

- reoperation
- explantation
- permanent disability
- death

6. CLINICAL STUDIES

The On-X® Prosthetic Heart Valve clinical trials were designed to study the safety and effectiveness of the valve in aortic valve replacement. Patients requiring isolated aortic heart valve replacement were enrolled from 1996 to 2000 at 11 centers in an international multicenter, prospective, non-randomized study with retrospective controls.

The cohort included 184 patients (121 men, 63 women), aged from 20 to 80 years (mean of 60.2 years). The cumulative follow-up was 411.8 patient-years with a mean follow-up of 2.2 years (SD = 0.8 years, range = 0 to 4.0 years). Tables 2 and 3 present preoperative and operative patient demographics. Figure 2 shows the number of patients implanted versus duration of follow-up. Table 4 presents implant information by valve size, including the number of patients implanted and the number of patient-years.

The safety endpoints captured in the studies were complications; blood analyses were used to confirm the absence or presence of certain complications. The safety results are provided above in Table 1. Effectiveness endpoints were New York Heart Association (NYHA) classification and echocardiographic assessments. NYHA and blood data were obtained pre-operatively, intra-operatively, and post-operatively at 3 to 6 months, at one year, and annually thereafter. Hemodynamic data were obtained at discharge and at one year. Tables 5 and 6 present these effectiveness results.

Table 2: Preoperative Patient Demographics
All patients implanted, N = 184, Cumulative follow-up = 411.8 patient-years

Patient Characteristic			n	% (n/N)[1]
Age at implant in years			60.2 ± 8.4	
Gender:	•	Male	121	65.8%
	•	Female	63	34.2%
NYHA Classification:	•	I	9	4.9%
	•	II	91	49.5%
	•	III	79	42.9%
	•	IV	5	2.7%
	•	Unknown	0	0.0%
Valve Lesion:	•	Stenosis	86	46.7%
	•	Insufficiency	39	21.2%
	•	Mixed	59	32.1%
	•	Other	0	0%

Notes:
1. n = number of patients in each category; N = total number of study patients.

Table 3: Operative Patient Demographics

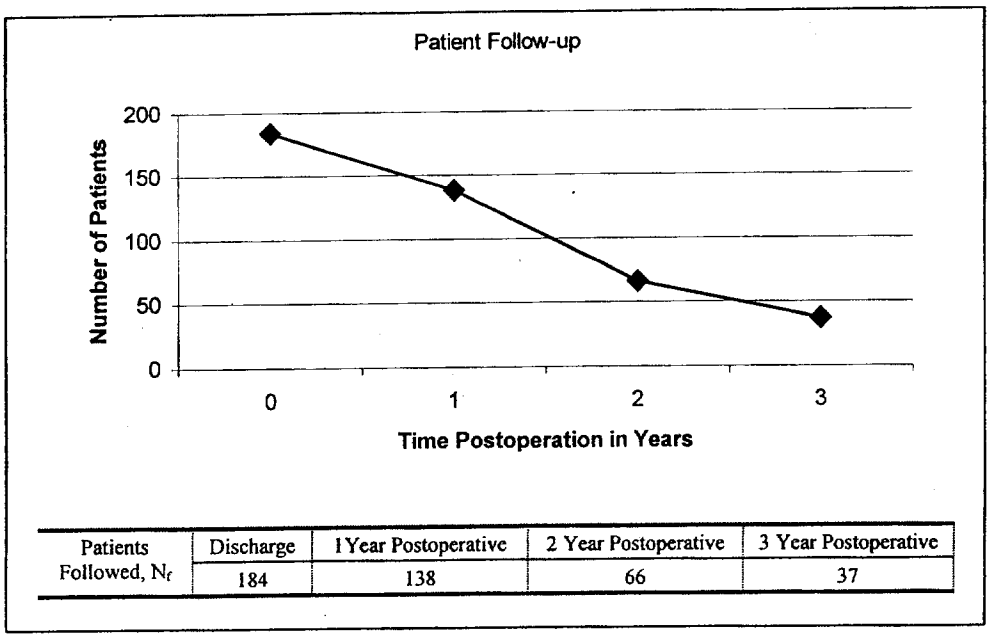
All patients implanted, N = 184, Cumulative follow-up = 411.8 patient-years

Variable	Category[1]	n	% (n/N)[2]
Etiology[3]	Calcific	92	50.0%
	Degenerative	51	27.7%
	Rheumatic	24	13.0%
	Congenital	18	9.8%
	Endocarditis	8	4.4%
	Prosthetic Valve Dysfunction	0	0.0%
	Other	6	3.3%
Concomitant Procedures[3]	None	141	76.7%
	Coronary Artery Bypass Graft	21	11.4%
	Myotomy	10	5.4%
	Mitral Repair	5	2.7%
	Aorta Repair or Replacement	4	2.2%
	Tricuspid Repair	1	0.5%
	Muscle Bridge	1	0.5%
	Tricuspid Replacement	0	0.0%
	Explant of Annuloplasty Ring	0	0.0%
	Maze Procedure	0	0.0%
	Closure of Atrial Appendage	0	0.0%
	Ventricular Aneurysm Repair	0	0.0%
	Other	0	0.0%
Pre-existing Conditions[3]	Systemic Hypertension	90	48.9%
	Hyperlipidemia	83	45.1%
	Angina	42	22.8%
	Coronary Artery Disease	42	22.8%
	Diabetes Mellitus	33	17.9%
	Atrial Arrhythmias	25	13.6%
	Left Ventricular Dysfunction	23	12.5%
	Congestive Heart Failure	22	12.0%
	Myocardial Infarction	12	6.5%
	Cerebrovascular Accident	10	5.4%
	Carotid Artery Disease	7	3.8%
	Endocarditis	4	2.2%
	Cardiomyopathy	3	1.6%
	Pacemaker Implant	2	1.1%
	Coronary Artery Bypass Graft	1	0.5%
	Previous Aortic Valve Replacement	1	0.5%
	Previous Mitral Valve Replacement	0	0.0%
	Other	27	14.8%
Valve Size	19 mm	17	9.2%
	21 mm	35	19.0%
	23 mm	70	38.0%
	25 mm	38	20.6%
	27/29 mm	24	13.0%

Notes:

1. Ordered by frequency of occurrence, except for valve size.
2. n = number of patients in each category; N = total number of study patients.
3. May be more than one per patient.

Figure 2: Patient Follow-up Over Time
All patients implanted, N = 184, Cumulative follow-up = 411.8 patient-years



Patients Followed, N_f	Discharge	1 Year Postoperative	2 Year Postoperative	3 Year Postoperative
	184	138	66	37

Table 4: Number of Patients Implanted and Number of Patient-years by Valve Size
All patients implanted, N = 184, Cumulative follow-up = 411.8 patient-years

	Numbers by Valve size					
	19 mm	21 mm	23 mm	25 mm	27/29 mm	Total
Number of Patients Implanted	17	35	70	38	24	184
Number of Patient-years	36.9	82.2	151.5	85.9	55.3	411.8

Table 5: Effectiveness Outcomes, Functional New York Heart (NYHA) Classification[1]
All patients implanted, N = 184, Cumulative follow-up = 411.8 patient-years

NYHA Class	Preoperative Assessment (N_d = 184)		Postoperative Assessments					
			1 Year (10-14 Months) (N_f = 138, N_d = 129)[2]		2 Year (22-26 Months) (N_f = 66, N_d = 66)		3 Year (34-38 Months) (N_f = 37, N_d = 36)	
	N[3]	% (n/N_d)	n	% (n/N_d)	n	% (n/N_d)	n	% (n/N_d)
I	9	4.9	83	60.1	48	72.7	20	54.0
II	91	49.5	35	25.4	12	18.2	10	27.0
III	79	42.9	4	2.9	6	9.1	4	10.8
IV	5	2.7	0	0	0	0	0	0
Undetermined[4]	0	0	7	5.1	0	0	2	5.4
Missing[5]	0	0	9	6.5	0	0	1	2.7

Notes:
1. Data does not include results from double valve replacement.
2. N_f = number of patients followed (reproduced from Figure 2); N_d = number of patients for which NYHA data were collected.
3. n = number of patients in each category.
4. Undetermined means data were collected but Class could not be determined during exam
5. Missing refers to the difference between the number of patients followed, N_f, and the number of patients for which NYHA data were collected, N_d.

Table 6: Effectiveness Outcomes, Hemodynamic Results[1]

All patients implanted, N = 184, Cumulative follow-up = 411.8 patient-years

Hemodynamic Parameter	Results by Valve Size									
	19 mm		21 mm		23 mm		25 mm		27/29 mm	
Early Postoperation (< 30 days), N_f = 184										
Mean Gradient[3]	N_d[4] = 20		N_d = 31		N_d = 58		N_d = 33		N_d = 20	
• Mean ± SD	11.6 ± 4.5		9.4 ± 3.6		8.4 ± 4.3		7.5 ± 3.8		6.1 ± 2.9	
• Min, max	5.6, 21.5		4.0, 18.4		2.0, 26.4		2.1, 18.6		1.0, 11.5	
EOA[5]	N_d = 19		N_d = 31		N_d = 57		N_d = 33		N_d = 20	
• Mean ± SD	1.4 ± 0.2		1.8 ± 0.3		2.1 ± 0.5		2.5 ± 0.8		2.8 ± 0.4	
• Min, max	1.1, 1.9		1.3, 2.4		1.0, 3.6		0.9, 4.3		1.9, 3.5	
Regurgitation[6]	N_d = 22		N_d = 40		N_d = 72		N_d = 38		N_d = 24	
	n[7]	% (n/N_d)	n	% (n/N_d)	n	% (n/N_d)	n	% (n/N_d)	n	% (n/N_d)
• 0	9	40.9%	14	35.0%	31	43.1%	19	50.0%	9	37.5%
• 1-2+	12	54.6%	25	62.5%	37	51.4%	19	50.0%	13	54.2%
• 3+	0	10.0%	0	0.0%	2	2.8%	0	0.0%	0	0.0%
• 4+	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
• Not available	1	4.6%	1	2.5%	2	2.8%	0	0.0%	2	8.3%
1 Year Postoperation, N_f = 138										
Mean Gradient	N_d = 13		N_d = 22		N_d = 55		N_d = 24		N_d = 16	
• Mean ± SD	9.7 ± 2.6		7.7 ± 2.8		6.6 ± 3.0		3.7 ± 2.2		5.6 ± 2.9	
• Min, max	5.7, 14.3		3.1, 15.2		2.0, 16.0		0.5, 11.3		1.0, 10.8	
EOA	N_d = 13		N_d = 22		N_d = 54		N_d = 25		N_d = 16	
• Mean ± SD	1.4 ± 0.3		1.9 ± 0.4		2.3 ± 0.6		2.8 ± 0.8		2.8 ± 0.6	
• Min, max	0.9, 1.8		1.2, 2.9		1.0, 4.1		0.8, 4.2		2.0, 4.1	
Regurgitation	N_d = 16		N_d = 28		N_d = 60		N_d = 30		N_d = 21	
	n	% (n/N_d)	n	% (n/N_d)	n	% (n/N_d)	n	% (n/N_d)	n	% (n/N_d)
• 0	4	25.0%	6	21.4%	24	40.0%	12	40.0%	5	23.8%
• 1-2+	11	68.8%	21	75.0%	33	55.0%	16	53.3%	15	71.4%
• 3+	0	0.0%	0	0.0%	2	3.3%	2	6.7%	1	4.8%
• 4+	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
• Not available	1	6.2%	1	3.6%	1	1.7%	0	0.0%	0	0.0%
> 1 Year Postoperation, N_f = 103 (total of 2 yr (66) and 3 yr (37) follow-up)										
Mean Gradient	N_d = 17		N_d = 29		N_d = 61		N_d = 30		N_d = 18	
• Mean ± SD	9.0 ± 3.2		8.1 ± 3.2		6.6 ± 3.1		4.2 ± 2.5		5.5 ± 3.0	
• Min, max	2.2, 14.3		3.5, 16.6		2.0, 14.1		0.8, 12.8		1.0, 10.8	
EOA	N_d = 17		N_d = 29		N_d = 60		N_d = 31		N_d = 18	
• Mean ± SD	1.5 ± 0.2		1.8 ± 0.5		2.3 ± 0.7		2.7 ± 0.8		2.9 ± 0.8	
• Min, max	0.9, 1.9		0.7, 2.9		1.4, 4.7		0.8, 4.2		2.0, 4.3	
Regurgitation	N_d = 20		N_d = 37		N_d = 68		N_d = 36		N_d = 25	
	n	% (n/N_d)	n	% (n/N_d)	n	% (n/N_d)	n	% (n/N_d)	n	% (n/N_d)
• 0	5	25.0%	9	24.3%	27	39.7%	17	47.2%	7	28.0%
• 1-2+	12	60.0%	25	67.6%	37	54.4%	16	44.4%	17	68.0%
• 3+	2	10.0%	0	0.0%	3	4.4%	2	5.6%	1	4.0%
• 4+	0	0.0%	0	0.0%	0	0.0%	1	2.8%	0	0.0%
• Not available	1	5.0%	3	8.1%	1	1.5%	0	0.0%	0	0.0%

Notes:

1. Hemodynamic evaluations were performed using transthoracic echocardiography (TEE) and in some cases, transesophageal echocardiography (TEE). Data does include results from double valve replacement.
2. N_f = number of patients followed (reproduced from Figure 2).
3. Mean gradient represents the pressure drop measured across the valve in mmHg.
4. N_d = number of patients for which hemodynamic data were collected.
5. EOA = effective orifice area measured in cm^2.
6. Regurgitation represents the valvular backflow of blood due to normal leakage and perivalvular leakage; 0 = none, 1+ = mild, 2+ = moderate, 3+ = moderate/severe, 4+ = severe.
7. n = number of patients in each category.

7. INDIVIDUALIZATION OF TREATMENT

Adequate anticoagulant or anticoagulant/antiplatelet therapy should be administered. Selection of an anticoagulant or anticoagulant/antiplatelet regimen is based on the particular needs of the patient and the clinical situation.

7.1 Specific Patient Populations

The safety and effectiveness of the On-X® Prosthetic Heart Valve has not been established for the following specific populations because it has not been studied in these populations:

- patients who are pregnant;
- nursing mothers;
- patients with chronic endocarditis;
- patients requiring pulmonic or tricuspid replacement.

8. PATIENT COUNSELING

- Prophylactic antibiotic treatment must be provided to all patients with prosthetic valves undergoing dental procedures or other potentially bacteremic procedures.

- Patients require anticoagulation or anticoagulant/antiplatelet therapy.

- Patients should be encouraged to complete the Patient ID card provided with the valve and carry it with them at all times.

9. HOW SUPPLIED

9.1 Available Models and Sizes

The On-X® Prosthetic Heart Valve is available in aortic sizes of 19 mm, 21 mm, 23 mm, 25 mm, and 27/29 mm. The 19 mm through 25 mm aortic valves are designed for supra-annular placement; the 27/29 mm aortic valve is designed for intra-annular placement.

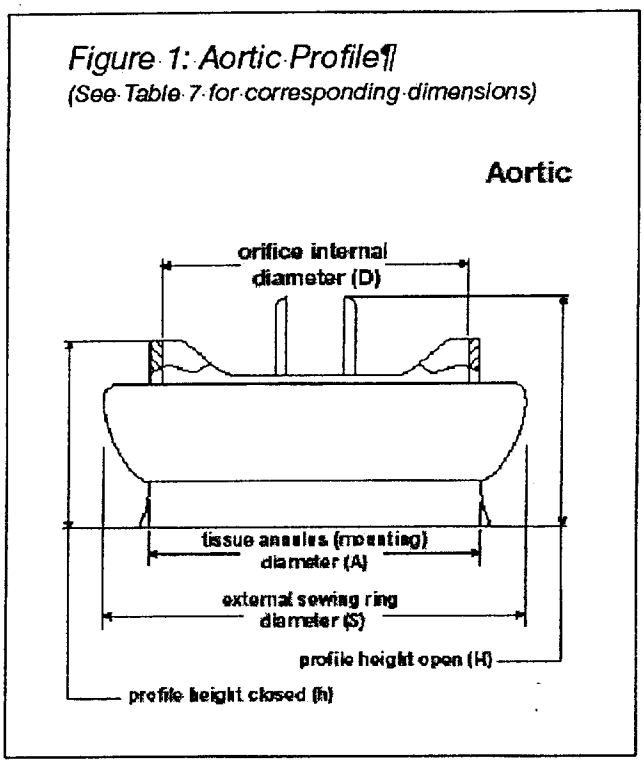
The dimensional and model specifications for all available sizes of the On-X® Prosthetic Heart Valve are shown in Table 7 and Figure 1. The symbol SZ mm on the box, container labels, and implant registration card refers to the tissue annulus diameter of the valve in millimeters.

Table 7: On-X® Valve Specifications (millimeters)

Model Designator	Size/Type	Tissue Annulus (mounting) Diameter	Orifice Internal Diameter	External Sewing Ring Diameter	Profile Height (closed)	Profile Height (open)	Internal Orifice Area
		(A)	(D)	(S)	(h)	(H)	(mm^2)
ONXA-19	19 Aortic	19	17.4	23.0	10.8	13.3	228
ONXA-21	21 Aortic	21	19.4	26.0	11.9	14.7	284
ONXA-23	23 Aortic	23	21.4	29.0	13.1	16.1	344
ONXA-25	25 Aortic	25	23.4	32.0	14.2	17.8	411
ONXA-27/29	27/29 Aortic	27-29	23.4	34.0	14.2	17.8	411

Refer to Figure 1 for location of measured dimensions. Values given are nominal within the tolerance band.

Figure 1: Aortic Profile
(See Table 7 for corresponding dimensions)



9.2 Packaging

The On-X® Prosthetic Heart Valve is provided sterile, mounted on a holder, in a double-sealed plastic container. The package consists of the following items:

- Outer box
- Plastic valve container
- Plastic valve holder
- Instructions for use
- Patient record card
- Implant registration card
- Valve serial number tag

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Instruments for implantation of the On-X® Prosthetic Heart Valve are supplied separately, **NON-STERILE**, and must be cleaned and sterilized prior to use as outlined in section 9.5.

9.3 Storage

The On-X® Prosthetic Heart Valve has been qualified for a maximum storage life of 5 years from the date of manufacture. The storage life of the On-X® Prosthetic Heart Valve is recorded on the outer package label. Appropriate inventory control should be maintained so that prostheses with earlier expiration dates are preferentially implanted and expiration is avoided. To protect the valve, it should be stored in its outer box until used. The storage environment should be clean, cool, and dry.

9.4 Accessories

The On-X® Prosthetic Heart Valve is designed to be used only with MCRI™ On-X® instruments. The instruments, supplied separately, are provided in a kit which include sizers, rotators, a universal instrument handle, and a universal leaflet probe. Sizers and rotators are available for each size On-X® Prosthetic Heart Valve. The instruments are reusable.

> **CAUTION**: Sizers and instrument handles have metallic regions that are bendable. Repeated bending of these metallic regions can lead to fatigue and fracture. To avoid instrument fracture during use, the stem should be inspected for surface cracks before and after each time it is bent. If metal fatigue surface cracks are present, the sizer and/or instrument handle should be discarded and replaced. Contact MCRI Customer Service to receive replacements.
>
> **CAUTION**: Leaflet probes and rotators are flexible, but are not intended to be bent to a permanently deformed state.

Sizer

The sizer is used to gauge the resulting tissue annulus diameter after the annulus is prepared for implant. The sizer has a bendable stem on each end. The sizers are cylindrical for size 19 mm through 25 mm valves and conical for size 27/29 mm valves (Figure 3A and 3B). To facilitate sizer selection, refer to Table 9.

Profile Sizers

The aortic profile sizer (Figure 3A) models the On-X® aortic valve profile. It is used after sizing to assure fit of the aortic valve without obstruction of the coronary arteries. Aortic profile sizers are provided for size 19 mm through 25 mm aortic valves, where the valve sewing ring is intended to remain supra-annular. The size 27/29 mm aortic valve is an intra-annular design, thus no profile sizer is supplied for this size valve.

Instrument Handle

The instrument handle (Figure 4) facilitates holding the valve or the rotator during surgery. The instrument handle is comprised of a grip, a bendable stem, and a tip.

The instrument handle tip is inserted into the valve holder while the valve is still in the package inner container. The tip is inserted into the valve holder by placing it directly into the slot on top of the valve holder. It snaps into place after the application of a light insertion force. Upon snapping into position, the valve and holder are firmly retained by the instrument handle. Removal of the valve from the inner container is performed after the valve holder is snapped onto the instrument handle.

Rotator

The valve rotator (Figure 5) is used for reorienting an *in situ* valve and may be used to verify leaflet mobility. The rotator consists of a plastic head with a centrally located leaflet mobility probe and an attached handle. The rotator is properly oriented for insertion into the valve when the cross-bar on the head is aligned with the leaflet pivot axis and the probe is inserted into the central orifice between the leaflets.

The rotator may be used with or without the instrument handle attached. To attach the rotator to the instrument handle, insert the instrument handle tip directly into the slot on the end of the rotator handle. The rotator snaps into place after the application of a light insertion force.

Leaflet Probe

The leaflet probe (Figure 6) is a flexible rod with tapered ends. The leaflet probe may be used to gently move the leaflets to verify that they open and close freely.

9.5 Accessory Cleaning and Sterilization

Instruments for implantation of the On-X® Prosthetic Heart Valve are supplied separately, **NON-STERILE**, and must be cleaned and sterilized prior to use. Standard hospital surgical instrument cleaning procedures must be used. Note: the metallic instruments are made of titanium or stainless steel. The plastic instruments are made of polyphenylsulfone, polysulfone, polyetherimide, polytetraflueroethylene, polyetheretherketone, or silicone. Materials used in these instruments can withstand standard steam and flash steam sterilization.

> **WARNING**: These instruments are NOT provided sterile. They must be properly cleaned and sterilized prior to each use.
>
> **WARNING**: DO NOT sterilize instruments with any method of sterilization other than steam. Damage to some items could result from use of other sterilization methods.
>
> **WARNING**: The rotator must be removed from the handle after use prior to cleaning. A force greater than the insertion force is required to remove the rotator from the instrument handle.

10. DIRECTIONS FOR USE

WARNING: DO NOT use the On-X® Prosthetic Heart Valve if:

- the prosthesis has been dropped, damaged, or mishandled in any way;
- the expiration date has elapsed;
- the tamper evident seal is broken;
- the serial number tag does not match the container label.

10.1 Physician Training

No special training is required to implant the On-X® Prosthetic Heart Valve. The techniques for implanting this prosthesis is similar to those used for any mechanical heart valve prosthesis.

10.2 Sterilization and Resterilization

The On-X® Prosthetic Heart Valve is provided sterile.

WARNING: DO NOT resterilize any On-X® Prosthetic Heart Valve:

- once it is removed from its plastic container;
- more than 3 times - resterilization of a valve which has passed the sterility expiration date is permitted, up to this limit, only if the valve has remained in the original unopened container and undamaged;
- with any method other than steam sterilization, with the identified resterilization parameters. Note: Gamma radiation is known to damage the sewing ring.

If the valve is removed from its plastic container but not used, it must not be repackaged or resterilized. In this situation, the valve must be returned to MCRI™. Call Customer Service for information before any return is made. If a valve is unused, its plastic container is undamaged, and the sterility expiration date has passed, the valve may be resterilized in its original plastic container using the conditions listed below:

Resterilization Parameters

Method:	Steam (Gravity)
Time:	60 minutes
Temperature:	121 - 123°C (250 - 258°F)
Pressure:	1.0 – 1.3 kg/cm² (15-18 psi)

The valve has been qualified for no more than 3 resterilization cycles. If the valve is resterilized, a new sterility expiration date must be applied to the label. This date shall be no longer than 1 year from the date of resterilization. Assurance of sterility after resterilization is the responsibility of the institution, not MCRI™.

10.3 Handling and Preparation Instructions

CAUTION: Handle the prosthesis with only MCRI™ 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.

CAUTION: 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.

CAUTION: Avoid damaging the prosthesis through the application of excessive force to the valve orifice or leaflets.

Circulating Nurse

1. Check the expiration date on the outer box.

   WARNING: DO NOT use the On-X® Prosthetic Heart Valve if the expiration date has elapsed. If a valve is unused, its plastic container is undamaged, and the sterility expiration date has passed, the valve may be resterilized in its original plastic container using the identified resterilization parameters.

2. Remove the valve container and package inserts from the outer box. Inspect the container for damage.

   WARNING: DO NOT use the On-X® Prosthetic Heart Valve if the prosthesis has been dropped, damaged, or mishandled in any way. If any damage is found, use another valve and arrange for a return through MCRI™ Customer Service.

3. Fill out the implant registration card as completely as local law allows and return to MCRI™ as soon as possible. This allows the patient to be entered into the tracking database, which could be important for future notices regarding the valve. Give the patient record card to the patient or place it in the patient's records.

4. Open the outer container by rotating its lid counter-clockwise until it stops, then lift the lid off of the container (Figure 7a).

5. The inner container can be placed on the sterile field by gently inverting the outer container slightly above the sterile field (Figure 7b) and allowing the inner container to slip out onto the sterile field. Alternately, the scrub nurse may remove the sterile inner container from the outer container by gently lifting the paper tab attached to the top of the inner container. The inner container is then placed onto the instrument tray.

Scrub Nurse/Surgeon:

1. Check the tamper evident seal of the inner container.

   WARNING: DO NOT use the On-X® Prosthetic Heart Valve if the tamper evident seal has been broken. If the tamper evident seal has been broken, use another valve and arrange for return through MCRI™ Customer Service.

2. Open the inner container by gently twisting the lid to break the tamper-proof seals (Figure 7c) and then lifting the lid off the base.

3. Take the instrument handle from the instrument kit and press its tip into the slot on the valve holder until it snaps firmly into position (Figure 7d). Gently lift the valve out of the container and slide the holder plate off the holder. Carefully grasp the sewing ring with a gloved hand using a light grip and gently turn the instrument handle in either direction. The valve should easily rotate within the ring. Stop rotation testing with an orientation mark aligned with the pivot axis.

   WARNING: DO NOT use the On-X® Prosthetic Heart Valve if the valve does not rotate easily. Use another valve and arrange for return through MCRI™ Customer Service.

4. Check the serial number tag against the label on the outer container.

   WARNING: DO NOT use the On-X® Prosthetic Heart Valve if the serial number tag does not match the container label. Use another valve and arrange for a return through MCRI™ Customer Service.

5. Remove the serial number tag by cutting the suture that holds it on the valve. If desired, the tag can be used to check for sterility by standard culture techniques immediately after it is removed.

6. The valve is now ready for implantation. To ease positioning during implantation, the instrument handle stem can be bent by grasping the ends of the handle and the stem, then bending. Avoid grasping the valve.

   WARNING: DO NOT use the valve for leverage in bending the instrument handle. This could damage the valve and lead to mechanical failure.

10.4 Device Implantation

Sizing

All accessory instruments must be cleaned and sterilized prior to use according to the instrument instructions. Use only On-X® Prosthetic Heart Valve sizers when sizing the annulus. The sizer set consists of cylindrical, conical, and aortic profile sizers. Refer to Table 9 to facilitate sizer selection.

The cylindrical sizers correspond to the valve sizes 19 mm through 25 mm. The conical sizers correspond to the valve size 27/29 mm.

The correct size annulus is determined by obtaining a comfortable, not tight, fit of the sizer within the annulus. When a comfortable fit is found, the corresponding valve size is signified by the identification on the sizer.

For size 19 mm through 25 mm aortic valves, the aortic profile sizers are used to verify that the aortic valve can be properly seated in the annulus and that the coronary arteries remain unobstructed. The size 19 mm through 25 mm aortic valves are designed to fit within the annulus at implant such that the exposed carbon flare rests in the annulus and the sewing ring is supra-annular (Figure 8).

> **WARNING**: DO NOT size the sewing ring of the size 19 mm through 25 mm aortic valve to fit within the annulus.

The size 27/29 mm aortic valve is designed to be placed in an intra-annular position and has no aortic profile sizer. Clearance of the conical sizer from the aortic structures indicates proper fit and clearance for size 27/29 mm aortic valve.

Table 9: Sizer Selection

Size (mm)	Sizer Choice		Position of sewing ring
	Sizer Type	Use Replicate Sizer	
19	Cylindrical	YES	Supra-annular
21	Cylindrical	YES	Supra-annular
23	Cylindrical	YES	Supra-annular
25	Cylindrical	YES	Supra-annular
27/29	Conical	NO	Intra-annular

> **CAUTION**: Avoid oversizing the valve, as this could lead to interference with valve function.

10.5 Suturing Techniques

Suturing techniques vary according to the preferences of the implanting surgeon and patient condition. The aortic valve is designed to have the tissue annulus abut the orifice flare. Also, the general consensus among surgeons is that the non-everting interrupted mattress suture technique, with or without pledgets, provides the best conformation of the valve annulus to the outer surface of the flare.

> **CAUTION**: When seating the valve, ensure that no suture material or anatomic structures interfere with leaflet motion. The valve's rotation capability may be helpful in avoiding abnormal residual pathology that could interfere with leaflet motion.

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The sutures should be passed through the outer half of the sewing ring. This allows the sewing ring to remain flexible and conform to the annulus. It also prevents the suture needle from contacting the titanium rings that lie within the sewing ring (Figure 9). The orientation marks on the sewing ring may be used to aid in suture placement.

When all the stitches are in place, the valve is advanced into the annulus and the sutures are tied down. For aortic valves, it is suggested that 3 knots be tied equidistant to one another and midway between the commissures to stabilize the valve in the annulus. The holder is removed from the valve by carefully cutting the retaining suture as shown in Figure 10, then gently lifting the valve holder with handle out of the valve.

> **WARNING**: Do NOT attempt to reinsert the valve holder into the valve once it has been removed.

> **CAUTION**: Suture ties should be cut short to avoid any potential interference with valve mechanics.

10.6 Leaflet Motion Assessment and Valve Rotation

Leaflet Motion Testing

Once the valve is in place, free motion of the leaflets must be tested. To test leaflet mobility, use the rotator probe or the leaflet probe to gently move the leaflets to verify that they open and close freely.

> **WARNING**: Test the leaflet mobility only with the MCRI™ On-X® individual leaflet probe or the leaflet probe on the end of the rotator.

Rotation

The rotator may be used with or without the instrument handle attached. As needed, attach the instrument handle to the rotator by inserting the instrument handle tip into the slot on the end of the rotator handle until it snaps firmly into position.

> **WARNING**: Use only the MCRI™ On-X® rotator to rotate the valve *in situ*. Use only the correspondingly sized rotator. Use of the wrong size rotator could damage the valve.

With the rotator probe between the leaflets and the cross-bar aligned with the leaflet pivot axis of the valve, carefully insert the valve rotator into the valve until it seats easily in place (Figure 11).

> **CAUTION**: No resistance should be experienced when inserting the rotator. If resistance is encountered, stop, remove, and realign the rotator before attempting to insert the rotator again.

Insert the probe tip into the central orifice to open the leaflets. If the leaflets do not move freely, gently rotate the valve in either direction until it reaches a position where leaflet interference is not encountered.

> **CAUTION**: Do not attempt to rotate the valve if any significant resistance to rotation is encountered. The torque required to rotate the valve *in situ* should be about the same as that required when testing rotation before implantation. If noticeably greater torque is required to rotate, stop attempting rotation. If leaflet interference exists and rotation cannot be achieved, remove the valve.

Retest leaflet motion. If free leaflet motion cannot be achieved, remove the valve.

10.7 Valve Orientation

Based on clinical studies, there is no preferred orientation for the On-X® Prosthetic Heart Valve.

> **CAUTION**: As with any aortic supra-annular valve, once the valve is implanted, visually confirm that the coronary ostia are free from potential interference.

11. POSTOPERATIVE INFORMATION

11.1 Magnetic Resonance Imaging (MRI) Compatibility

The On-X® Prosthetic Heart Valve has been shown to be MRI safe when tested using systems operating with shielded static magnetic field strengths of 1.5 Tesla or less. Note, however, that the effects of a time-varying magnetic field were not examined. The testing should not cause significant MRI image artifacts or distortion – should this occur, this phenomenon produces no harmful effects to the patient.

11.2 Returned Goods

Prior authorization from MCRI™ Customer Service is required for the return of any product. For any questions regarding the valve or for return authorization, please contact Customer Service.

Licensed under U.S. Patent Nos. 5,308,361; 5,137,532; 5,545,216; 5,772,694; 5,641,324; 5,908,452; 5,284,676; 5,305,554; 5,328,713, 5,332,337; 5,336,259; 5,514,410; 5,677,061; 6,096,075; Serial No. 09/010,449 allowed; Serial No. 09/224,816 allowed; and other permits and patents pending.

12. PATIENT INFORMATION

12.1 Patient Registration

In each valve package, there is a *Patient Record Card* and an *Implant Registration Card.* MCRI™ requests that the *Implant Registration Card* be filled out immediately and that the mailing copy be returned to MCRI™ Customer Service. For multiple valve implants, please fill out a card for each valve. MCRI™ will use these data for notification purposes and to help with inventory restocking in the hospital. All patient information remains strictly confidential, and the release of patient-identifying information can be refused if allowed by law.

12.2 Patient Record Card

A *Patient Record Card* is provided with the prosthesis. Patients should be encouraged to complete the card and carry it with them at all times.

12.3 Patient Information Booklet

MCRI™ has made available a patient information booklet that the physician may choose to provide to the patient prior to discharge. Copies of this booklet are available on request from your MCRI™ sales representative.

13. DISCLAIMER OF WARRANTIES

Because of the complications listed previously that may occur with the use of any heart valve prosthesis and the possibilities of damage, also noted previously, before, during or after implantation, MCRI™ warrants only that the product shall conform to MCRI™'s standard specifications. No other warranty is made by MCRI™ concerning the function of the product in use, and MCRI™ assumes no risk whatsoever as to the results of the use of this product. The entire risk with use of the product is that of the buyer. MCRI™ disclaims all other warranties, respecting the product, expressed or implied, including but not limited to those related to the product's merchantability or fitness for a particular purpose. MCRI™ shall not be liable for any direct, special, consequential or incidental loss, damage or expense related to the use of the product. No person has any authority to alter any of these conditions or to bind MCRI™ to any additional responsibility or warranty in connection with the use of the product.

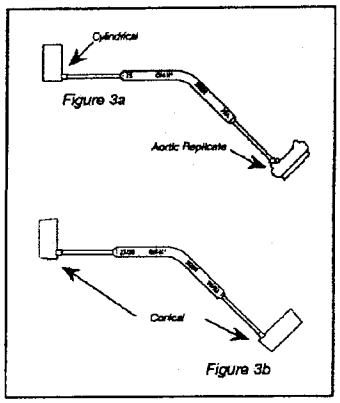


Figure 3a

Figure 3b

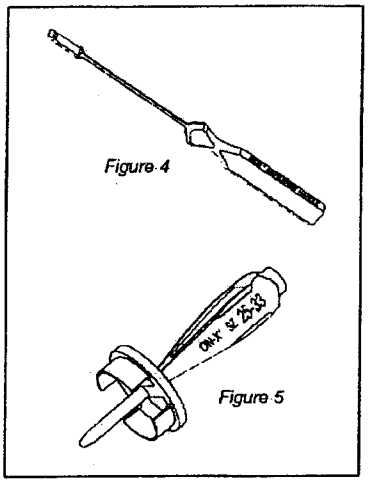
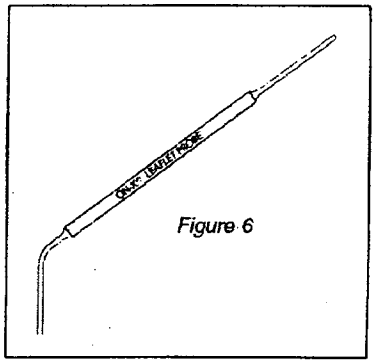


Figure 4

Figure 5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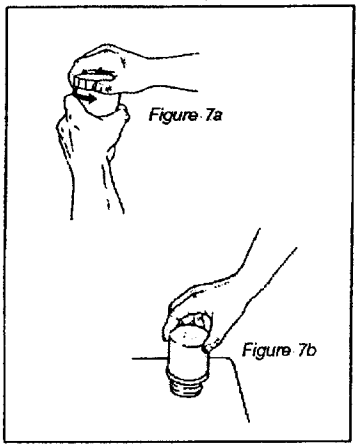


Figure 7a

Figure 7b

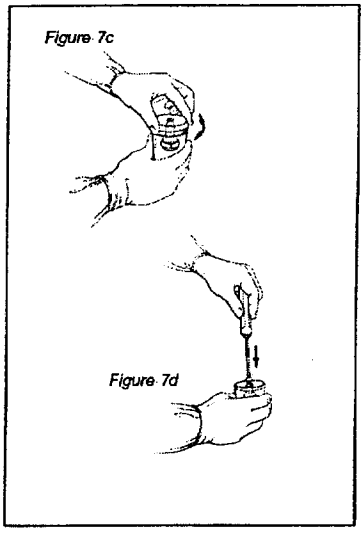
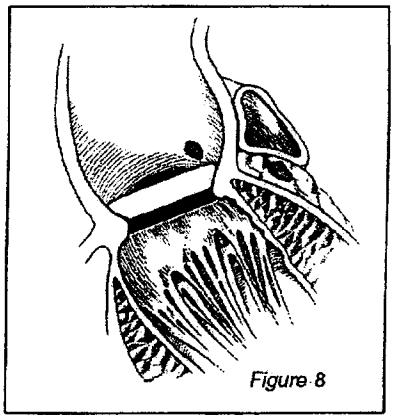


Figure 7c

Figure 7d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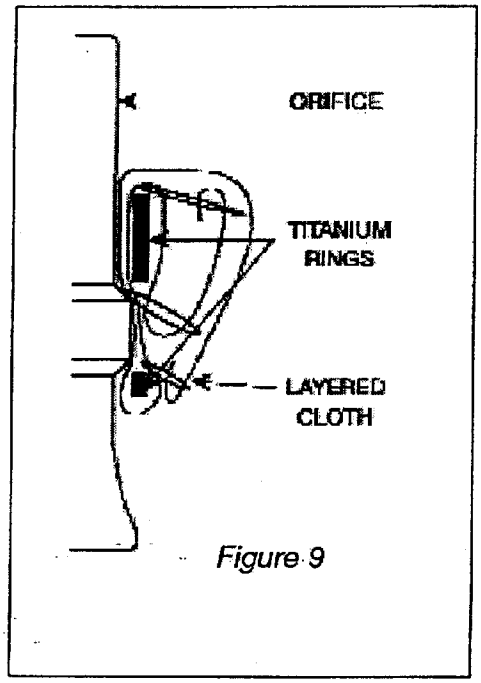

Figure 9

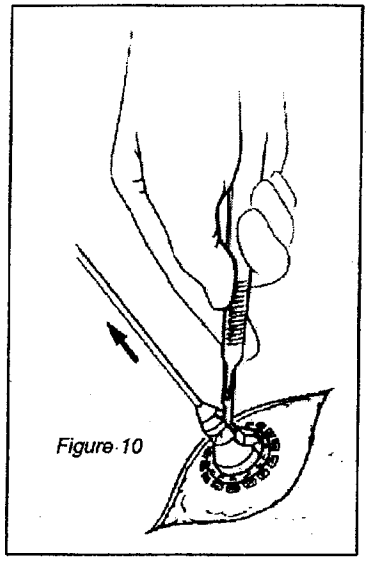
Figure 10

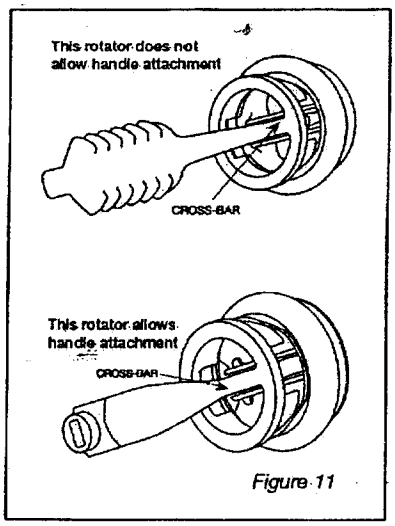

Figure 11