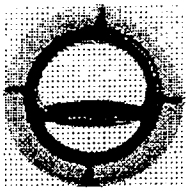
OMNICARBON™ CARDIAC VALVE PROSTHESIS

INSTRUCTIONS FOR HANDLING AND USE

CONTENTS

Medical CV Inc



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

OMNICARBON™ AORTIC PROSTHESES, Model 3313				
Size (corresponds to tissue annulus diameter, TAD, mm)	23	25	27	29
Disc Diameter (mm)	18	20	22	22
IntraAnnular Suture Ring (with 3 suture guide markers)				

OMNICARBON™ MITRAL PROSTHESES, Model 3523				
Size (TAD, mm)	27	29	31	33
Disc Diameter (mm)	22	22	24	24
SupraAnnular Suture Ring (with 4 suture guide markers)				

1.0 DEVICE DESCRIPTION

The Omnicarbon™ cardiac valve prosthesis is an all pyrolytic carbon-coated mechanical-type valve prosthesis, with a single tilting disc. The valve design has three major components: the housing ring, disc, and suture ring.

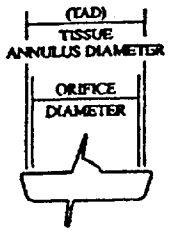
The disc is fabricated from pyrolytic carbon thickly coated over a graphite substrate containing tungsten (to allow radiographic visualization). The disc is slightly curved and retained within the housing ring by integral pivots and shields. The shields are small, fin-like structures projecting downstream from the housing ring, located 180° from each other on either side of the housing ring. The disc closes on the housing ring at a 12° angle relative to the plane of the housing ring, and can open to a maximum angle of 80°. The disc rotates freely within the housing ring because there are no fixed hinges within the housing ring. Because there are no struts protruding across the flow orifice, the open disc separates the flow channel into two orifices.

The suture ring is constructed of polytetrafluoroethylene (PTFE). The seamless white fabric contains three (aortic) or four (mitral) black polyester markers to assist with suture placement during implantation. To allow optimal orientation of the prosthesis after implantation, the housing ring/disc assembly is rotatable within the suture ring.

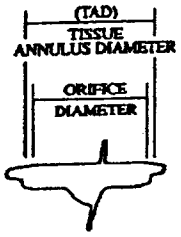
The Omnicarbon™ cardiac valve prosthesis is available in aortic and mitral configurations. The aortic valve, model 3313, is available in sizes 23, 25, 27, and 29 mm. The aortic valve suture ring has an intra-annular configuration. The mitral valve, model 3523, is available in sizes 27, 29, 31, and 33 mm. The mitral valve has a supra-annular suture ring. Flow area dimensions of these valve sizes are listed in Figure 1. Sizes 27 and 29 share the same housing ring/disc assembly, with the suture ring compensating for the difference in tissue annulus diameter. Likewise, sizes 31 and 33 also employ identical housing ring/disc assemblies.

Figure 1
Omnicarbon™ Cardiac Valve Sizes

Aortic



Mitral



Size (corresponds to tissue annulus diameter, mm):	23	25	27	29	31	33
Disc Diameter, mm	18	20	22	22	24	24
Geometric Orifice Area, cm^2	2.5	3.1	3.8	3.8	4.5	4.5

2.0 INDICATIONS FOR USE

The Omnicarbon™ cardiac valve prosthesis is indicated for the replacement of dysfunctioning, native or prosthetic, aortic or mitral heart valves.

3.0 CONTRAINDICATIONS

The Omnicarbon™ cardiac valve prosthesis is contraindicated for patients unable to tolerate anticoagulation therapy.

4.0 WARNINGS AND PRECAUTIONS

4.1 Warnings

For single use only. Do not resterilize.

If the Use-Before-Date on the package has expired, do not use the valve.

Carefully examine the labels and seals of the outer and inner packaging. If the accuracy or integrity of *any* of these labels or seals is in doubt, do not use this valve.

All accessory equipment must be disassembled after each use and thoroughly cleaned prior to resterilization. Routinely examine accessory equipment for damage or distortion prior to each use.

The outside of the rigid plastic exterior container (hardpack) is not sterile and must not be placed in the sterile field.

Dropped Valve: If you drop the valve, do not implant it.

Chipped or Scratched Valve Housing Ring or Disc: If the valve housing ring or disc is chipped or scratched, do not implant the valve.

Disengaged Disc: This may be caused by undetected handling damage or extreme pressure on the disc. Should disengagement occur, do not attempt to re-engage the disc into the valve housing; the valve should not be implanted.

Valves that have Come in Contact with Blood: Do not attempt to clean and resterilize such a valve for use in another person. Foreign protein transfer and/or residue from cleaning agents may cause a tissue reaction.

Catheterization: Passing a catheter, surgical instrument, or pacemaker lead through the Omnicarbon™ valve may cause serious valvular insufficiency, damage the valve, and/or cause catheter entrapment and, therefore, is not recommended.

4.2 Precautions

The innerpack and its contents are provided nonpyrogenic and sterile, and should be handled during surgical presentation with all necessary precautions to avoid contamination.

Oversizing occurs when too large a valve is forced into the tissue annulus. This may cause adjacent tissue to inhibit the free movement and full travel of the valve disc. If the obturator head does not pass easily through the tissue annulus, utilize the next lower size.

Use only OmniSeries/Omnicarbon accessories with the Omnicarbon™ valve.

Use only the OmniSeries™ collet or rotator to rotate the Omnicarbon™ valve. Under *no* circumstances should a surgical instrument be used to grasp the valve housing ring or disc. The valve disc should never be used as a lever to rotate the valve. Improper force or leverage on the disc may cause surface/structural damage or disc dislodgement.

No hard, sharp instruments should come in contact with the disc or valve housing ring. They may cause scratches or other surface imperfections which may result in blood injury, thrombus formation, and/or structural damage.

Soiled Valves: A valve soiled by fingerprints or foreign materials should not be implanted. This condition may cause clotting or blood damage.

The disc and housing ring are nonpyrogenic, sterile, and have a high polish. It is recommended that they be handled only by the gloved hand (free of glove powder). Contact of the polished surfaces with metallic or abrasive instruments during handling and implantation must be avoided.

Grease, fingerprints, or scratches may engender thrombus formation, structural damage, and/or blood injury.

Rotation of the valve after implantation should be done only when absolutely necessary, such as when subannular abnormalities interfere with free disc movement. Valve rotation should not be regarded as a routine procedure, since the valve may be damaged and/or the sutures may loosen causing perivalvular leak.

The most critical insertion parameter is to position the valve in an orientation that permits free movement and full travel of the disc.

When implanting an aortic valve, ensure that the suture ring does not block the coronary ostia.

Oblique implantation of aortic prostheses can cause disc opening angle overtravel in certain orientations, with resulting excessive regurgitation or intermittent nonclosure of the disc. Therefore, care should be taken with all pivoting-disc prostheses to ensure that the disc does not open beyond the axis of flow.

Emergency Procedures: Patients with implanted Omnicarbon™ valves are exposed to a risk of valve damage or malfunction due to certain emergency cardiovascular procedures, such as external cardiac massage or balloon pump support.

5.0 ADVERSE EVENTS

5.1 Potential Adverse Events

Adverse events potentially associated with the use of mechanical prosthetic cardiac valves include, but are not limited to (in alphabetical order):

- angina
- cardiac arrhythmia
- clinically-significant transvalvular regurgitation
- disc impingement/entrapment
- endocarditis or other infection
- heart failure
- hemolysis or hemolytic anemia
- hemorrhage
- myocardial infarction
- nonstructural dysfunction
- perivalvular leak
- stroke
- structural dysfunction
- thromboembolism
- tissue interference with valve function
- valve thrombosis

These events may lead to:

- permanent disability
- prosthesis explantation
- reoperation
- death

5.2 Observed Adverse Events

A multicenter, nonrandomized, prospective, international clinical study was conducted of patients implanted with an aortic and/or a mitral Omnicarbon™ cardiac valve prosthesis from August 27, 1984 through January 31, 1986. This study enrolled 354 patients at 5 institutions: 198 isolated aortic valve replacement (AVR), 115 isolated mitral valve replacement (MVR), and 41 aortic and

mitral (double) valve replacement (DVR). Results of this initial clinical study were reported at 33 months, at which time the total cumulative follow-up was 555 patient-years.

Clinical results were updated at 4 of the initial study centers, creating a 14.6-year follow-up study. (The fifth center did not participate due to logistical reasons.) These long-term results included 232 patients (125 AVR, 70 MVR, 37 DVR), with a mean follow-up time of 9.9 ± 4.7 years (range 0.3 – 14.6 years) and 91% patient accountability. Total cumulative follow-up time of 2,152 patient-years was distributed as 1,198 AVR patient-years, 598 MVR patient-years, and 356 DVR patient-years. Adequate follow-up time was obtained for all three groups.

Table 1 shows the observed adverse events occurring during the early postoperative period.

Table 1
Early Postoperative Adverse Events
n (% of cases)

Event	AVR (125 pts.)	MVR (70 pts.)	DVR (37 pts.)
Death, all causes	4 (3.2)	6 (8.6)	2 (5.4)
Thromboembolism, All	5 (4.0)	0	0
Thromboembolism, TIA	2 (1.6)	0	0
Thromboembolism, Nontransient	3 (2.4)	0	0
Valve Thrombosis	0	1 (1.4)	0
Anticoagulant-Related Hemorrhage, major	0	1 (1.4)	0
Endocarditis	1 (0.8)	0	0
Perivalvular Leak, major	1 (0.8)	0	1 (2.7)
Pannus/Tissue Interference	0	0	0
Hemolytic Anemia	0	0	0
Structural Failure	0	0	0
Unacceptable Hemodynamics	0	0	0
Other Nonstructural Dysfunction	0	0	0
Reoperation	2 (1.6)	1 (1.4)	1 (2.7)
Explantation	2 (1.6)	1 (1.4)	0

Abbreviations: n = number of patients, pts. = patients
AVR = aortic valve replacement, MVR = mitral valve replacement, DVR = double valve replacement
TIA = transient ischemic attack

Table 2 lists linearized rates of late postoperative events for the patients-at-risk of each patient group. During the 14.6-year period, 69 patients died due to various causes. Valve replacement associated mortality was defined as death due to thromboembolism (7 cases), anticoagulant-related hemorrhage (5), sudden and unknown causes of death (8), endocarditis (3), perivalvular leak (3), and nonstructural dysfunction (1). The actuarial probabilities of freedom from adverse events at 5, 10, and 14 years are listed in Tables 3 and 4.

Table 2

Late Postoperative Events: Linearized Rates, %/patient-year ± SE (# of events)

	AVR	MVR	DVR
Patient-Years	1,198	598	356
Death, all causes	3.17±0.51 (38)	3.34±0.75 (20)	3.09±0.93 (11)
Death, valve-related/unexplained	1.34±0.33 (16)	0.67±0.33 (4)	1.97±0.74 (7)
Thromboembolism, All	0.92±0.28 (11)	0.33±0.24 (2)	0.56±0.40 (2)
Thromboembolism, TIA	0.25±0.14 (3)	0.33±0.24 (2)	0.28±0.28 (1)
Thromboembolism, Nontransient	0.67±0.24 (8)	0	0.28±0.28 (1)
Valve Thrombosis	0	0.17±0.17 (1)	0
Anticoagulant-Related Hemorrhage, major	0.67±0.24 (8)	0.50±0.29 (3)	0.56±0.40 (2)
Endocarditis	0.58±0.22 (7)	0	0.28±0.28 (1)
Perivalvular Leak, major	0.92±0.28 (11)	0.50±0.29 (3)	1.12±0.56 (4)
Pannus/Tissue Interference	0	0	0
Hemolytic Anemia	0	0	0
Structural Failure	0	0	0
Unacceptable Hemodynamics	0	0	0
Other Nonstructural Dysfunction	0.08±0.08 (1)	0.17±0.17 (1)	0
Reoperation	1.42±0.34 (17)	0.84±0.37 (5)	1.12±0.56 (4)
Explantation	1.09±0.30 (13)	0.67±0.33 (4)	0.28±0.28 (1)
Other: Minor Bleeding (no treatment)	0.58±0.22 (7)	0.67±0.33 (4)	0.84±0.49 (3)
Other: Perivalvular Regurgitation Without Hemodynamic Consequence (by echo)	0.42±0.19 (5)	0.17±0.17 (1)	0.84±0.49 (3)

Abbreviations: AVR = aortic valve replacement, MVR = mitral valve replacement, DVR = double valve replacement
TIA = transient ischemic attack

Table 3

Late Postoperative Events: Actuarial Probability of Freedom from Event (life table method)
% ± SE at 5, 10, and 14 years Postoperative: Aortic Valve Replacement

Aortic Valve Replacement (AVR): cumulative follow-up = 1,198 patient-years			
Event	**Freedom at 5 years**	**Freedom at 10 years**	**Freedom at 14 years**
Death, all causes	82.8 ± 3.5	75.2 ± 4.1	63.7 ± 4.9
Thromboembolism, All	97.3 ± 1.5	92.6 ± 2.7	85.6 ± 4.3
Thromboembolism, TIA	99.1 ± 0.9	97.9 ± 1.5	95.6 ± 2.7
Thromboembolism, Nontransient	98.1 ± 1.3	94.5 ± 2.4	89.8 ± 3.6
Valve Thrombosis	100	100	100
Anticoagulant-Related Hemorrhage, major	96.4 ± 1.8	94.0 ± 2.4	92.7 ± 2.7
Endocarditis	94.1 ± 2.2	94.1 ± 2.2	94.1 ± 2.2
Perivalvular Leak, major	95.7 ± 1.9	94.6 ± 2.2	91.0 ± 3.3
Pannus/Tissue Interference	100	100	100
Hemolytic Anemia	100	100	100
Structural Failure	100	100	100
Unacceptable Hemodynamics	100	100	100
Other Nonstructural Dysfunction	99.1 ± 0.9	99.1 ± 0.9	99.1 ± 0.9
Reoperation	90.8 ± 2.7	89.7 ± 2.8	89.7 ± 2.8
Explantation	91.6 ± 2.6	90.5 ± 2.8	90.5 ± 2.8

Table 4

Late Postoperative Events: Actuarial Probability of Freedom from Event (life table method)
% ± SE at 5, 10, and 14 years Postoperative: Mitral Valve Replacement

Mitral Valve Replacement (MVR): cumulative follow-up = 598 patient-years			
Event	**Freedom at 5 years**	**Freedom at 10 years**	**Freedom at 14 years**
Death, all causes	89.7 ± 4.0	70.5 ± 6.2	62.4 ± 6.7
Thromboembolism, All	98.4 ± 1.6	98.4 ± 1.6	95.3 ± 3.5
Thromboembolism, TIA	98.4 ± 1.6	98.4 ± 1.6	95.3 ± 3.5
Thromboembolism, Nontransient	100	100	100
Valve Thrombosis	98.4 ± 1.6	98.4 ± 1.6	98.4 ± 1.6
Anticoagulant-Related Hemorrhage, major	96.8 ± 2.2	96.8 ± 2.2	93.8 ± 3.7
Endocarditis	100	100	100
Perivalvular Leak, major	100	93.0 ± 3.9	93.0 ± 3.9
Pannus/Tissue Interference	100	100	100
Hemolytic Anemia	100	100	100
Structural Failure	100	100	100
Unacceptable Hemodynamics	100	100	100
Other Nonstructural Dysfunction	100	97.6 ± 2.4	97.6 ± 2.4
Reoperation	98.4 ± 1.6	89.3 ± 4.6	89.3 ± 4.6
Explantation	98.4 ± 1.6	91.3 ± 4.2	91.3 ± 4.2

6.0 CLINICAL STUDIES

Description of the long-term clinical study reported in Section 5.2 is presented here. Table 5 contains demographic data, Table 6 has operative information, and Tables 7 and 8 display hematology and hemodynamic (echocardiography) data. These laboratory data were acquired approximately 13½ years postoperatively. Table 9 shows improvement of preoperative NYHA functional classification in the long-term clinical study patients. The clinical study did not generate sufficient data to support the safety and effectiveness of sizes 19, 21, 31, and 33 aortic valves and sizes 19 – 25 mitral valves.

Table 5

Population Demographics

Patients	232 (125 AVR, 70 MVR, 37 DVR)	
Gender	167 males, 65 females	
Age at Implantation	49 ± 12 years (range 14 – 71) AVR: 49 ± 13, MVR: 50 ± 11, DVR: 49 ± 11	
Disease Etiology (some patients experienced multiple conditions):		
	Rheumatic	54%
	Endocarditis	10%
	Prosthetic Valve Dysfunction	9%
	Congenital	9%
	Myxomatous/Mucinous	4%
	Marfan Syndrome	3%
	Cystic Medial Necrosis	1%
	Other (e.g., calcification, trauma)	13%
	Undetermined	4%
Preoperative NYHA Classification	2% I 26% II 57% III 14% IV 1% undetermined	

Table 6
Operative Information

Previous Cardiac Surgical Procedures:		number of patients
	Coronary Artery Bypass Graft	2
	Previous Prosthetic Valve	20
	Aortic Graft	1
	Commissurotomy	11
Concomitant Cardiac Surgical Procedures:		
	Coronary Artery Bypass Graft	15
	Aortic Graft	12
	Aortic Root Reconstruction	4
	Aneurysm Repair	1
	Annuloplasty	12
	Commissurotomy	3
	Permanent Pacemaker	2
	Miscellaneous (e.g., ASD/VSD repair)	15
Implant Distribution	AVR 54%, MVR 30%, DVR 16%	
Valve Size (includes DVR)	Aortic (# of patients)	Mitral (# of patients)
21 mm	7	0
23 mm	73	2
25 mm	46	21
27 mm	29	44
29 mm	7	32
31 mm	0	8

Table 7
Late Postoperative Blood Values by Implant Position

Parameter	AVR mean±SD	MVR mean±SD	DVR mean±SD
Hemoglobin, males, *g/dL*	14.8±1.4	14.2±2.2	14.2±1.9
Hemoglobin, females, *g/dL*	13.6±1.0	14.1±1.2	13.2±1.7
Hematocrit, males, *%*	44±4	42±6	42±5
Hematocrit, females, *%*	40±2	41±3	39±5
Red Blood Cells, males, $10^6/\mu L$	4.86±0.61	4.77±0.65	4.50±0.63
Red Blood Cells, females, $10^6/\mu L$	4.42±0.27	4.54±0.38	4.29±0.65
Reticulocytes *% RBC*	1.3±0.6	1.1±0.5	2.2±1.6
White Blood Cells $10^3/\mu L$	7.0±1.8	6.7±1.7	6.5±1.7
Lactate Dehydrogenase *% upper normal*	97±28	109±38	142±61
Haptoglobin *% lower normal*	48±71	83±120	29±34

Table 8
Hemodynamics:
Doppler Echocardiography Values of Mean Pressure Gradient and Effective Orifice Area
Mean ± Standard Deviation [range] (sample size)

Size	Cardiac Output (L/min)	Mean Gradient (mmHg)	Effective Orifice Area (cm^2)
AORTIC			
21	7.50 [7, 8] (2)	36 ± 4 [32 - 41] (4)	1.30 ± 0.10 [1.2 - 1.4] (3)
23	6.15 ± 1.80 [2.5 - 10] (27)	19 ± 8 [3.7 - 36] (40)	1.78 ± 0.94 [0.9 - 5.49] (31)
25	6.42 ± 1.92 [2.2 - 9] (11)	16 ± 8 [3 - 30] (20)	1.92 ± 0.84 [1 - 4.17] (15)
27	5.87 ± 2.61 [3.59 - 8.9] (4)	12 ± 4 [5.7 - 21] (14)	2.45 ± 1.40 [0.95 - 4.4] (6)
29	— (0)	9 ± 3 [7 - 13.7] (4)	— (0)
MITRAL			
25	4.26 ± 1.13 [3.3 - 5.5] (4)	9 ± 3 [5.3 - 16] (9)	1.70 ± 0.39 [1.2 - 2.4] (9)
27	5.54 ± 1.95 [3.2 - 9] (11)	5 ± 3 [2.1 - 19.5] (23)	1.89 ± 0.47 [1.4 - 3.4] (16)
29	6.50 ± 1.85 [4.3 - 10] (7)	5 ± 2 [2.5 - 7.8] (11)	1.64 ± 0.17 [1.38 - 1.85] (8)
31	5.68 ± 1.66 [3.97 - 9.0] (3)	6 ± 2 [3.5 - 7.3] (3)	1.95 ± 0.67 [1.4 - 2.69] (3)

Note: Sizes 27 and 29 mm have the same flow orifice dimensions (same disc/housing ring size), with only a larger suture ring making up the size difference. Similarly, sizes 31 and 33 have the same flow orifice dimensions, however, no size 33 mm valves were implanted in this study.

No regurgitation was seen in 37% of the aortic valve studies. Regurgitation was observed in 57% of the aortic valve cases, and no mention of regurgitation was made in 6%. No regurgitation was seen in 54% of the mitral valve studies. Regurgitation was observed in 29% of the mitral valve cases, and no mention of regurgitation was made in 17% of the studies. Most regurgitation (87% of aortic and 50% of mitral) was recorded as having trivial intensity. Severe regurgitation was not observed.

Table 9
NYHA Classification Comparison

Class	Preoperative		14.6-yr Study	
AORTIC				
I	3%	(4/125)	72%	(49/68)
II	42%	(53/125)	27%	(18/68)
III	42%	(52/125)	2%	(1/68)
IV	11%	(14/125)	0%	
Unknown	2%	(2/125)		
MITRAL				
I	0%		80%	(24/30)
II	10%	(7/70)	10%	(3/30)
III	67%	(47/70)	10%	(3/30)
IV	23%	(16/70)	0%	
DOUBLE (Aortic and Mitral)				
I	0%		41%	(7/17)
II	3%	(1/37)	41%	(7/17)
III	92%	(34/37)	18%	(3/17)
IV	5%	(2/37)	0%	

Echocardiography data also were obtained from another large foreign institution, separate from the 14.6-year clinical study. These data were collected at a mean postoperative time of 6.1 years for aortic valves and 5.3 years for mitral valves. Table 10 displays a summary of the estimated mean transvalvular gradient, effective orifice area, and cardiac output for each valve size.

Table 10
Doppler Echocardiography Values of Mean Pressure Gradient and Effective Orifice Area
Mean ± Standard Deviation [range]

Size	n	Cardiac Output (L/min)	Mean Gradient (mmHg)	Estimated Orifice Area (cm^2)
AORTIC				
21	6	4.60 ± 0.91 [3.40 - 5.81]	15 ± 11 [3 - 35]	1.40 ± 0.56 [0.62 - 2.27]
23	23	5.12 ± 1.31 [3.30 - 8.29]	14 ± 7 [3 - 36]	1.25 ± 0.24 [0.88 - 1.83]
25	75	4.97 ± 1.54 [2.50 - 8.90]	13 ± 5 [2 - 33]	1.53 ± 0.45 [0.72 - 2.92]
27	5	5.98 ± 1.85 [4.50 - 8.68]	10 ± 5 [4 - 17]	2.27 ± 0.99 [1.15 - 3.74]
29	2	5.12 [4.42, 5.82]	8 [8, 8]	1.55 [1.26, 1.83]
MITRAL				
27	26	4.69 ± 1.58 [2.65 - 8.73]	3 ± 1 [2 - 4]	2.63 ± 0.62 [1.61 - 4.31]
29	76	5.12 ± 1.48 [1.96 - 9.04]	3 ± 1 [1 - 9]	2.55 ± 0.73 [1.46 - 5.00]
31	9	4.90 ± 1.78 [2.59 - 8.29]	3 ± 1 [2 - 4]	2.88 ± 0.78 [1.69 - 4.06]

Note: Sizes 27 and 29 mm have the same flow orifice dimensions (same disc/housing ring size), with only a larger suture ring making up the size difference. Similarly, sizes 31 and 33 have the same flow orifice dimensions, however, no size 33 mm valves were implanted in this study.

7.0 TREATMENT INDIVIDUALIZATION AND PATIENT COUNSELING

Safety and effectiveness of the Omnicarbon™ cardiac valve prosthesis 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 requiring pulmonary or tricuspid valve replacement

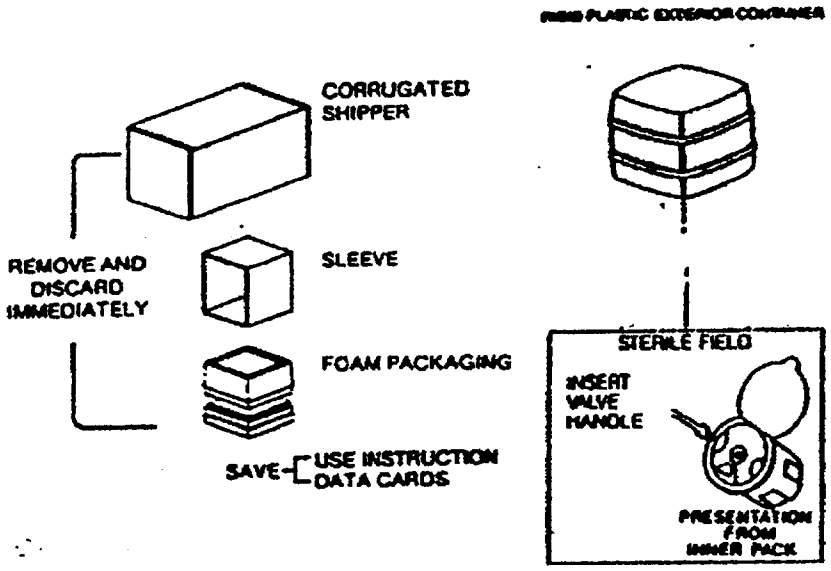
Adequate anticoagulation or anticoagulation/antiplatelet therapy should be administered to persons with a mechanical prosthetic cardiac valve, unless medically contraindicated. Also, prophylactic antibiotic treatment should be given to prosthetic valve patients undergoing dental or other potentially bacteremic procedures. Patients should carry their Implanted Device Identification Card with them at all times (refer to Section 11). The Omnicarbon™ cardiac valve prosthesis presents no substantial or increased risk for magnetic resonance imaging (MRI).

8.0 HOW SUPPLIED

8.1 Packaging

Omnicarbon™ cardiac valve prostheses are sterilized using ethylene oxide by the manufacturer and are supplied in a special packaging system (Figure 2), which provides protection from mechanical damage during shipment. The innerpack contents are sterile and nonpyrogenic.

Figure 2
OmniSeries™ Package System



Omnicarbon™ aortic valves have russet (a red color) labels, and mitral valves have dark taupe (gray-brown) labels. Besides the valve and its containers and labels, *Instructions for Handling and Use* and an Implantation Data Card are included with each valve package.

Accessories to facilitate valve implantation are available—these include obturators, valve holders, and rotators. Accessories are provided nonsterile and must be thoroughly cleaned and sterilized prior to use. Refer to Section 9 for detailed information.

8.2 Storage

Immediately upon receipt of the valve, remove and discard the corrugated shipping carton, paperboard sleeve, and semi-rigid plastic foam elements. This will expose the data band on the exterior container, showing all technical data for the prosthesis, including the "Use-Before-Date." Two microbiological barriers protect the sterilized prosthesis prior to use:

a. a rigid plastic exterior container (hardpack)
b. an inner package (innerpack) with a sealed lid

It is recommended that the valve be stored in its exterior plastic container in a clean, dry location at room temperature (approximately 5° – 32° C/41° – 90° F). Unused, sterile valves within their undamaged original innerpacks will maintain their sterility until at least the "Use-Before-Date." **CAUTION: If the Use-Before-Date on the package has expired, do not use the valve.**

9.0 IMPLANTATION ACCESSORIES

Implantation accessory equipment (obturators, valve holders, and rotators) is provided by the manufacturer NONSTERILE, and must be thoroughly cleaned and sterilized prior to initial use. The accessories and their storage tray are reusable. Use only Omnicarbon™ or OmniSeries™ accessory equipment with Omnicarbon™ prosthetic valves. Other brands or types of accessory equipment may damage the prosthesis.

Obturators (valve sizers) match the outer diameter of the Omnicarbon™ valve (i.e., tissue annulus diameter) for selection of the appropriate valve size, and valve holders facilitate handling of the valve during suturing and implantation. The rotator may be used to reorient an Omnicarbon™ valve after implantation (see Section 10.5). Refer to the *Instructions for Use* provided with Omnicarbon™ or OmniSeries™ accessory equipment for full descriptions of the instruments and their model numbers.

CAUTION: Accessory equipment must be disassembled after each use and thoroughly cleaned prior to resterilization. Routinely examine accessory equipment for damage or distortion prior to each use.

9.1 Cleaning of Accessories

Follow the cleaning instructions of your institution, or clean the accessories according to the following directions. Inspect all accessories for damage, distortion, or residues after cleaning.

a. Disassemble each rotator and the curved handle.
b. Place the accessory equipment in an enzymatic cleaning solution, prepared according to label directions. Soak the pieces for 5 minutes.
c. Clean each piece by scrubbing, and then wipe all surfaces with a water-moistened towel.
d. Rinse each piece with distilled or reverse osmosis water for a minimum of 15 seconds.
e. Place each piece on clean towels and allow to air dry.

f. Reassemble the curved handle and rotators. Adjust the rotators to their smallest size. Sterilize (see Section 9.2).
More detailed instructions are given in the *Instructions for Use* provided with each set of implantation accessories.

9.2 Sterilization of Accessories
a. The accessory equipment may be sterilized by conventional (121° C/250° F, 30 minutes) or flash (132° C/270° F, 10 minutes) steam sterilization, or by ethylene oxide (EO) gas exposure (725 mg/L, 55° C/131° F, 70% RH, 60 minutes). Follow the recommendations for sterilization commonly used by your clinical facility or consult the Omnicarbon™ accessories' *Instructions for Use*.
b. Accessory equipment may be subjected to multiple resterilization by either EO gas or steam.
CAUTION: Do not resterilize the Omnicarbon™ valve.

10.0 DEVICE IMPLANTATION

10.1 Selection of Valve Size
CAUTION: Use only Omnicarbon or OmniSeries obturators with the Omnicarbon™ valve. For Omnicarbon™ valves, use obturators (sizers) marked "OMNI" or "Omnicarbon", since the dimensions correspond to Omnicarbon™ valve suture rings. (Refer to Section 9 for information about preparation of the obturators.) The obturators can measure either the aortic or mitral position. The proper size obturator will fit the annulus in a manner that is comfortable, being neither a too snug nor a too loose fit. The number engraved on the obturator corresponds to the nominal valve size.

Give consideration to the potential for postoperative myocardial recovery and ventricular size reduction. Also, be mindful that cardioplegia may temporarily make the heart flaccid. Deviation from normal sizing may be medically indicated.

CAUTION: Oversizing occurs when too large a valve is forced into the tissue annulus. This may cause adjacent tissue to inhibit the free movement and full travel of the valve disc. If the obturator does not pass easily through the tissue annulus, utilize the next lower size.

10.2 Valve Handling and Preparation Instructions
CAUTION: Carefully examine the labels and seals of the outer and inner packaging. If the accuracy or integrity of *any* of these labels or seals is in doubt, do not use this valve.

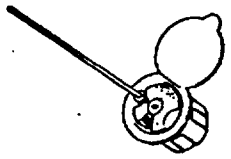
The innerpack and its contents are provided nonpyrogenic and sterile, and should be handled during surgical presentation with all necessary precautions to avoid contamination.

The outside of the rigid plastic exterior container (hardpack) is not sterile and must not be placed in the sterile field.

a. Remove the integrity seal and data label from the perimeter of the hardpack.

b. Verify that all valve data (serial number, type, and size) are identical on both the hardpack data label and on the innerpack data label.
c. Open the hardpack by lifting the top cover. The contents of the hardpack are sterile, and should be handled in an aseptic manner to prevent contamination.
d. Remove the sealed innerpack, containing the valve, from the hardpack. For surgical presentation, peel back the lid to open the innerpack, and attach a sterile OmniSeries valve holder (Figure 3).

Figure 3
Valve Holder Attachment



e. Remove the valve/collet assembly from the innerpack.
f. Grasp the finger-indent of the collet retaining clip. Tilt the clip downward toward the handle (away from the valve) and withdraw the clip (see Figure 4).

Figure 4
Removal of Collet Retaining Clip

g. Pre-Implant Valve Rotation:
Although the valve mechanism has been designed to rotate inside the suture ring, sterilization may cause the materials used in construction of the suture ring to take a "set." This may cause the torque force needed to initiate suture ring rotation (threshold torque) to exceed the original "as-manufactured" tolerances. To circumvent difficulties from this condition, rotate every valve prior to implantation.

Carefully rotate the suture ring by hand at least one full revolution in each direction prior to implantation as a standard preparation procedure. Accomplish this by encircling the suture ring with the thumb and index finger of one hand (sterile-gloved) and rotating the valve by turning the collet in a slow, steady movement with the other hand. Care should be taken not to release the collet latch. This procedure should produce a low threshold torque.

10.3 Valve Implantation

CAUTION: The disc and housing ring are nonpyrogenic, sterile, and have a high polish. It is recommended that they be handled only by the gloved hand (free of powder). Contact of the valve surfaces with metallic or abrasive instruments during handling and implantation

must be avoided. Grease, fingerprints, or scratches may engender thrombus formation, structural damage, and/or blood injury.

Do not use a valve that has been mishandled in any way. Refer to the warnings and precautions listed in Section 4. Section 10.1 discusses the process for selection of the appropriate valve size. Use only Omnicarbon/OmniSeries accessories when handling the valve (see Section 9).

To assist in rapid uniform placement of sutures, the suture rings on the Omnicarbon™ valves are prepared with either three (aortic) or four (mitral) equally-spaced guide markers. If desired, the suture ring may be rotated on the prosthesis just prior to implantation (see Section 10.2.g) in order to position the markers with respect to the natural cusps and to align the pivoting axis of the disc to a selected orientation.

If attachment sutures are placed deeply into the suture ring, the natural elastic compliance of the fabric will be compromised and additional stress may be imposed upon the supporting tissue. Care must be taken to assure that no pledgets, knots, or tails from attachment sutures can interfere with the disc movement.

CAUTION: The most critical insertion parameter is to position the valve in an orientation that permits free movement and full travel of the disc.

The disc may be tested for free movement by using a soft, lint-free fabric or a plastic-covered/rubber shod instrument. If free disc movement is inhibited, or if tissue encroachment is observed, the valve should be reoriented and/or any obstruction removed. If the interference is not alleviated by this treatment, repositioning of the valve may be necessary to avoid valve malfunction (refer to Section 10.5).

CAUTION: No hard, sharp instruments should come in contact with the disc or valve housing ring. They may cause scratches or other surface imperfections which may result in injury, thrombus formation, and/or structural damage.

10.3.1 Aortic Valve Implantation

The Omnicarbon™ valve may be implanted in any orientation that does not inhibit free movement of the disc. A study comparing orientation positions demonstrated better hemodynamics when the larger orifice of a monoleaflet valve is directed toward the noncoronary leaflet (±45°).[1] Care should be taken that the interventricular septum or other tissue does not interfere with disc movement.

CAUTION: When implanting the aortic valve, ensure that the suture ring does not block the coronary ostia.

CAUTION: Oblique implantation of aortic prostheses can cause disc opening angle overtravel in certain orientations, with resulting excessive regurgitation or intermittent nonclosure of the disc.[2,3] Therefore, care should be taken with all pivoting-disc prostheses to ensure that the disc does not open beyond the axis of flow.

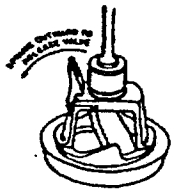
10.3.2 Mitral Valve Implantation

The Omnicarbon™ valve may be implanted in any orientation that does not inhibit free movement of the disc. A study reported slightly better hemodynamics when the larger orifice of a monoleaflet valve is directed posteriorly (away from the left ventricular outflow tract),[4] while other physicians prefer to avoid any chance of disc interference with the myocardium by orienting the larger orifice toward the aortic outflow tract (anteriorly).[5,6] In some cases, this anterior orientation may be necessary to avoid impingement on retained papillary structures.

10.4 Collet Removal

The collet is usually left in place on the valve until the sutures are tied. (In some cases, the surgeon may elect to remove the collet before the sutures are tied.) To remove the collet, spring the latch outward, away from the valve holder, as pictured in Figure 5. Rock the collet gently to remove it from the valve.

Figure 5
Release Latch for Valve Collet Removal



10.5 Valve Rotation Post Implant

CAUTION: Rotation of the valve after implantation should be done only when absolutely necessary, such as when subannular abnormalities interfere with free disc movement. Valve rotation should not be regarded as a routine procedure, since the valve may be damaged and/or the sutures may loosen, causing perivalvular leak.

After all sutures have been tied, the valve housing may be rotated, if necessary, within the suture ring using the attached collet or an OmniSeries valve rotator. Simultaneously stabilize the suture ring by counterforce with a forceps during this rotation so as not to exert excessive tension upon the sutures, which could lead to perivalvular leak.

CAUTION: Use only the OmniSeries collet or rotator to rotate the Omnicarbon™ valve. Under *no* circumstances should a surgical instrument be used to grasp the valve housing ring or disc. The valve disc should never be used as a lever to rotate the valve. Improper force or leverage on the disc may cause surface/structural damage or disc dislodgement.

11.0 PATIENT INFORMATION

The Implantation Data Card forms the basis for recording vital prosthetic implant data. Immediately after implantation of the prosthesis, enter the valve model number and complete serial number (or affix one of the tracking labels), along with other patient information, on the Implantation Data Card. The valve model and serial numbers are printed on labels on both the

innerpack and the hardpack, as well as on the small tracking labels included with each valve package.

After recording all required data, distribute copies of the Implantation Data Card to the following records:

Green: Operating Room
Yellow: Hospital
Blue: Surgeon
White: Mail to MedicalCV, Inc.

After receipt of this information, MedicalCV, Inc. will prepare and return to the surgeon a wallet-size Implanted Device Identification Card, which should be given to the patient. Patients should be encouraged to carry the Identification Card with them at all times. Implantation information will also be entered into the company's database to assist with tracking of the prosthetic valve. Registration of Omnicarbon™ valve implantation is required by United States regulation.

12.0 CREDIT AND RETURN POLICY

12.1 Returned Product Information

Return of any product—with the exception of recovered clinical specimens—to MedicalCV, Inc. for any reason must be authorized in writing by the company. Product returned without such authorization will not be accepted.

12.2 Return of Explanted Valve

Return of explanted prostheses for scientific evaluation are accepted by the Medical Affairs Department without prior approval. Please contact MedicalCV, Inc. for information regarding acceptable storage and transport of such specimens. Specific studies of the explanted device may be performed upon its return.

13.0 CUSTOMER SERVICE

If emergency shipping or technical information is required, MedicalCV, Inc. can be reached 24 hours per day, 7 days per week, in the United States by telephone at +1-651-452-3000, or during office hours by telefax at +1-651-452-4948.

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WARRANTY

In view of the nature of intracardiac prosthetic devices and procedures in which they are used, MedicalCV, Inc. makes no warranty expressed or implied by operation of law or otherwise, beyond the warranty that at the time of manufacture due care was used in the manufacture and choice of materials for the product.

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MedicalCV, Inc.
9725 South Robert Trail
Inver Grove Heights, Minnesota 55077
USA
Telephone: +1-651-452-3000
Telefax: +1-651-452-4948

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