ATS OPEN PIVOT® BILEAFLET HEART VALVE
Instructions for Use

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

1. DEVICE DESCRIPTION

The ATS Open Pivot® Bileaflet Heart Valve is a low profile bileaflet valve consisting of pyrolytic carbon orifice ring and leaflets (Figures 1 and 2).

The prosthesis consists of an orifice housing two mirror image leaflets. The low profile of the prosthesis results from the bileaflet design where the pivot areas are located entirely within the orifice ring, which minimizes the overall height of the valve. Pivot guides located on the inner circumference of the orifice ring control the range of leaflet motion. The pivot geometry consists of arc-shaped notches at either end of each leaflet and spherical protrusions at four places on the orifice. Each leaflet rotates around two opposing spheres. There are inflow and outflow stops adjacent to each sphere on the orifice which limit the rotation of the leaflets. There are no recesses or cavities in the pivot area. In the closed position, the plane of each leaflet forms a nominal angle of 25° relative to the plane of the orifice ring. In the fully open position, the plane of each leaflet forms a nominal angle of 85° relative to the plane of the orifice ring.

The leaflets consist of pyrolytic carbon coated over a graphite substrate. The graphite substrate is impregnated with 20% tungsten for radiopacity. The orifice consists entirely of pyrolytic carbon.

The valve sewing cuff is constructed of double velour polyester fabric and is mounted on the orifice using a titanium stiffening ring and secured with two titanium lock rings and a lock wire. This method of sewing cuff attachment to the orifice allows for rotation of the sewing cuff *in situ,* during surgical placement. The sewing cuff of mitral sizes 29, 31, and 33 mm contains a polytetrafluoroethylene (PTFE) liner inside the double velour polyester fabric.

The ATS Open Pivot® Bileaflet Heart Valve is available in the aortic and mitral configurations in two sewing cuff styles, the Standard and Advanced Performance (AP) styles. The AP model, with a reduced cuff, is a supra-annular configuration of the Standard model. The ATS Open Pivot® Bileaflet Heart Valve Standard model (Figure 1) is available in sizes 21 through 29 mm in the aortic position (Model 500FA), and sizes 29 through 33 mm in the mitral position (Model 500DM). The ATS Open Pivot® Bileaflet Heart Valve AP model (Figure 2) is available in sizes 18 through 26 mm in the aortic position (Model 501DA), and sizes 26 and 28 mm in the mitral position (Model 501DM). The ATS Open Pivot® Bileaflet Heart Valve dimensions are listed in Table 1.

Three cuff markers are located in the aortic cuff and four cuff markers are located in the mitral cuff to assist in the uniform placement of sutures around the valve annulus.

Table 1: Valve Dimensions

Model #		Overall Profile Height (mm)	Inflow Profile Height (mm)	Outflow Profile Height (mm)	Inside Diameter (mm)	Outside Diameter (mm)	Orifice Area (cm^2)
Aortic							
Standard							
21A	500FA21	10.3	2.9	7.4	16.8	21.5	2.02
23A	500FA23	11.3	3.4	7.9	18.8	23.5	2.56
25A	500FA25	12.3	3.1	9.2	20.8	25.5	3.17
27A	500FA27	13.3	3.4	9.9	22.8	27.5	3.84
29A	500FA29	14.3	3.9	10.4	24.8	29.5	4.59
Advanced Performance (AP)							
18A – AP	501DA18	10.3	1.5	8.8	16.8	18.2	2.02
20A – AP	501DA20	11.3	1.5	9.8	18.8	20.2	2.56
22A – AP	501DA22	12.3	1.5	10.8	20.8	22.2	3.17
24A – AP	501DA24	13.3	1.5	11.8	22.8	24.2	3.84
26A - AP	501DA26	14.3	1.5	12.8	24.8	26.2	4.59
Mitral							
Standard							
29M	500DM29	14.3	3.7	10.6	24.8	29.5	4.59
31M	500DM31	15.4	3.7	11.7	26.8	31.5	5.35
33M	500DM33	15.4	3.7	11.7	26.8	33.5	5.35
Advanced Performance (AP)							
26M – AP	501DM26	14.3	3.7	10.6	24.8	26.2	4.59
28M – AP	501DM28	15.4	3.7	11.7	26.8	28.2	5.35

2. INDICATIONS FOR USE

The ATS Open Pivot® Bileaflet Heart Valve is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic or mitral valves.

3. CONTRAINDICATIONS

The ATS Open Pivot® Bileaflet Heart Valve is contraindicated in patients unable to tolerate anticoagulation therapy.

4. WARNINGS

- FOR SINGLE USE ONLY.
- Avoid damaging the prosthesis. Only handle the prosthesis with the accessories provided by ATS Medical. Touching of the valve with gloved fingers or any surgical instrument may cause damage to the valve surface not seen with the unaided eye that may lead to accelerated valve structural deterioration or leaflet escape, or serve as a nidus for thrombus formation.
- Do NOT pass a catheter through the prosthesis as this may cause valvular insufficiency or disc dislodgment, or catheter entrapment.
- Do NOT apply force to the leaflets, attempt to change the position of the leaflets, or remove a leaflet.

5. PRECAUTIONS

Precautions Prior to Use

- Do NOT use the ATS Open Pivot® Bileaflet Heart Valve if the prosthesis has been dropped, damaged, or mishandled in any way. Should the valve be damaged during implantation or removal from the package, do not use for implantation.

- Do NOT use the ATS Open Pivot® Bileaflet Heart Valve if the tamper evident seal is broken, or if the expiration date has elapsed.

- Do NOT resterilize any ATS Open Pivot® Bileaflet Heart Valve.

Precautions During Use

- Use only the ATS Medical Valve Sizer to select the proper valve size as other sizers may result in improper valve selection.

- 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.

6. ADVERSE EVENTS

A total of 965 ATS Open Pivot® Bileaflet Heart Valves were implanted in 965 patients at 20 centers. The mean follow-up was 1.4 years (range 0 to 5 years) with a total of 1323 patient-years.

A total of 56 deaths occurred during the study and 20 of these were characterized as valve-related. The causes of valve-related deaths were endocarditis (2 patients), paravalvular leak (1 patient), thromboembolism (3 patients), anticoagulant-related hemorrhage (10 patients), and unknown (4 patients).

6.1. Observed Adverse Events

Table 2 shows the observed adverse events for early events (occurring ≤ 30 days post-implant), the linearized rates for late events (occurring >30 days post-operatively), and the actuarial adverse event rates at one and 5 years post-operatively.

Table 2: Observed Adverse Events

	Early Events % of pts. (N)	Late Events %/pt-yr. (N)	Actuarial Freedom by Kaplan-Meier 1 Year [95% CI]	5 years [95% CI]
Aortic Valve Replacement, All patients implanted: N= 685, Cumulative Follow-up= 866.4 patient years				
Deaths (all causes)	2.04% (14)	2.77% ± 1.06% (24)	.9735 [± .01]	.9031 [± .05]
Death (valve-related/unexplained)	0.58% (4)	1.15% ± 0.74% (10)	.9817 [± .01]	.9539 [± .03]
Anticoagulant-Related Hemorrhage (All)	4.67% (32)	1.96% ± 0.91% (17)	.9781 [± .01]	.9340 [± .04]
Anticoagulant-Related Hemorrhage (Major)	3.21% (22)	1.27% ± 0.76% (11)	.9878 [± .01]	.9473 [± .04]
Thromboembolism (All)	1.75% (12)	2.08% ± 0.93% (18)	.9733 [± .01]	.9283 [± .05]
Permanent Neurological Events	0.88% (6)	0.69% ± 0.60% (6)	.9920 [± .01]	.9706 [± .04]
Transient Neurological Events	0.88% (6)	1.39% ± 0.78% (12)	.9812 [± .01]	.9564 [± .03]
Valve Thrombosis	0.00% (0)	0.00% ± 0.00% (0)	1.000 [± .00]	1.000 [± .00]
Perivalvular Leak (All)	0.15% (1)	0.46% ± 0.52% (4)	.9966 [± .00]	.9898 [± .01]
Perivalvular Leak (Major)	0.15% (1)	0.12% ± 0.33% (1)	.9983 [± .00]	.9983 [± .00]
Endocarditis	0.00% (0)	0.35% ± 0.46% (3)	.9960 [± .01]	.9908 [± .01]
Hemolysis	0.00% (0)	0.00% ± 0.00% (0)	1.000 [± .00]	1.000 [± .00]
Structural Dysfunction	0.00% (0)	0.00% ± 0.00% (0)	1.000 [± .00]	1.000 [± .00]
Nonstructural Dysfunction	0.00% (0)	0.00% ± 0.00% (0)	1.000 [± .00]	1.000 [± .00]
Reoperation	0.15% (1)	0.35% ± 0.46% (3)	.9961 [± .01]	.9914 [± .01]
Explant	0.00% (0)	0.23% ± 0.41% (2)	.9978 [± .00]	.9931 [± .01]
Mitral Valve Replacement, All patients implanted: N=280, Cumulative Follow-up= 374.7 patient years				
Deaths (all causes)	1.79% (5)	3.47% ± 1.88% (13)	.9814 [± .02]	.8099 [± .11]
Death (valve-related/unexplained)	0.71% (2)	1.07% ± 1.19% (4)	.9831 [± .02]	.9342 [± .07]
Anticoagulant-Related Hemorrhage (All)	3.21% (9)	0.53% ± 0.95% (2)	.9958 [± .01]	.9673 [± .06]
Anticoagulant-Related Hemorrhage (Major)	3.21% (9)	0.53% ± 0.95% (2)	.9958 [± .01]	.9673 [± .06]
Thromboembolism (All)	3.21% (9)	4.00% ± 2.00% (15)	.9534 [± .03]	.8589 [± .09]
Permanent Neurological Events	1.79% (5)	0.80% ± 1.08% (3)	.9910 [± .01]	.9807 [± .02]
Transient Neurological Events	1.43% (4)	3.20% ± 1.82% (12)	.9621 [± .03]	.8758 [± .09]
Valve Thrombosis	0.00% (0)	0.53% ± 0.95% (2)	.9947 [± .01]	.9866 [± .02]
Perivalvular Leak (All)	0.71% (2)	1.07% ± 1.19% (4)	.9819 [± .02]	.9819 [± .02]
Perivalvular Leak (Major)	0.36% (1)	0.53% ± 0.95% (2)	.9915 [± .01]	.9915 [± .01]
Endocarditis	0.36% (1)	0.53% ± 0.95% (2)	.9957 [± .01]	.9861 [± .02]
Hemolysis	0.00% (0)	0.53% ± 0.95% (2)	.9952 [± .01]	.9814 [± .03]
Structural Dysfunction	0.00% (0)	0.00% ± 0.00% (0)	1.000 [± .00]	1.000 [± .00]
Nonstructural Dysfunction	0.00% (0)	0.00% ± 0.00% (0)	1.000 [± .00]	1.000 [± .00]
Reoperation	0.71% (2)	1.07% ± 1.19% (4)	.9874 [± .01]	.9697 [± .03]
Explant	0.36% (1)	0.53% ± 0.95% (2)	.9959 [± .01]	.9783 [± .03]

Notes:

1. Cumulative probability of freedom from event estimate at the end of the interval (Pc) is based on the Kaplan-Meier method.
2. The 95% confidence interval bound for the cumulative freedom rate at the end of the interval = 1.96 X SE, where SE is the standard error estimate of the cumulative probability of freedom from study heart valve related or unexplained event estimate calculated using Greenwood's formula.
3. The actuarial hazard rate estimates are calculated at the midpoint of each interval.
4. The 95% confidence interval bound for the hazard rate at the midpoint of each interval = 1.96 X SE, where SE is the standard error estimate of the hazard rate estimate at the midpoint of the interval.

6.2. Potential Adverse Events

Adverse events potentially associated with the use of prosthetic heart valves (in alphabetical order) include:

- cardiac arrhythmias
- death
- leaflet entrapment (impingement)
- endocarditis
- hemolysis
- hemorrhage, anticoagulation-related
- leak, transvalvular or perivalvular
- prosthesis thrombosis
- structural deterioration
- valve thromboembolism

7. CLINICAL STUDIES

Patients requiring isolated aortic or mitral heart valve replacement were enrolled from 1994 to 1999 at 20 centers (17 domestic and 3 international) in a multicenter, international, prospective, non-randomized study. NYHA classification 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 was obtained at discharge and at one year. Patients were monitored throughout the post-operative period for possible adverse events. The antiplatelet and anticoagulant agents used were reported. Target INRs were as follows: mitral position, 2.5 to 3.5, and aortic position, 2.0 to 3.0 (when in normal sinus rhythm).

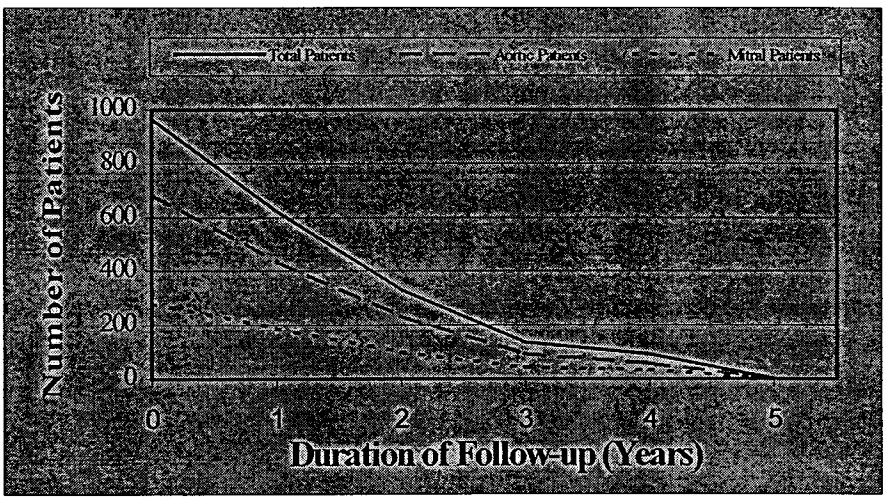
The cohort included 965 patients (580 men, 385 women), aged from 2 to 88 years (mean of 60.7). The cumulative follow-up was 1323 patient-years with a mean follow-up of 1.4 years (SD = 1.2 years, range=0 to 5.0 years). Table 3 shows patient characteristics by age, gender, and etiology of valve disease.

Table 3: Patient Characteristics
All patients implanted, N = 965, 1323 patient-years

Description of Patients	Aortic Valve N = 685 (70.98%)	Mitral Valve N = 280 (29.02%)
Age at implant in years		
0-9	5 (0.7%)	6 (2.1%)
10-19	4 (0.6%)	0 (0.0%)
20-29	11 (1.6%)	2 (0.7%)
30-39	33 (4.8%)	14 (5.0%)
40-49	72 (10.5%)	31 (11.1%)
50-59	142 (20.7%)	52 (18.6%)
60-69	238 (34.7%)	107 (38.2%)
70-79	155 (22.6%)	62 (22.1%)
80 & over	25 (3.6%)	6 (2.1%)
Gender		
Male	460 (67.2%)	120 (42.9%)
Female	225 (32.8%)	160 (57.1%)
Etiology of valve disease		
Stenosis	541 (79.0%)	118 (42.1%)
Insufficiency	330 (48.2)	210 (75.0%)
Mixed	205 (29.9%)	63 (22.5%)
Other	12 (1.8%)	12 (4.3%)

Figure 3 shows the number of patients implanted versus duration of follow-up in the graphic with a breakdown by valve location (aortic and mitral). Table 4 shows the number of patients implanted for whom hemodynamic data was collected. Table 5 shows the number of patient-years by implant size and location. Tables 6 through 10 show effectiveness outcomes.

Figure 3: Number of Patients by Implant Location over Time
All patients implanted, N=965



Year	0	1	2	3	4	5
Total Patients	965	624	331	135	92	2
Aortic Patients	685	436	231	93	58	2
Mitral Patients	280	188	100	42	34	0

Table 4: Number of Patients Implanted and Maximum Number of Patients with Hemodynamic Data at > 6 Months Follow-up

By implant location and valve size, n[1] = 493, N=965

Implant Location	Valve size (mm)							
	16/19	18/21	20/23	22/25	24/27	26/29	28/31/33	Total
Aortic (N/n)	23/9	100/61	202/108	206/113	111/70	39/32	4/4	685/397
Mitral (N/n)	0/0	3/1	5/4	3/2	23/8	71/39	175/106	280/160
Total (N/n)	23/9	103/62	207/112	209/115	134/78	110/71	179/110	965/557

Note:

1. n = number of patients with hemodynamic data; N = number of patients implanted

Table 5: Number of Patient-Years by Implant Location and Valve Size

By implant location and valve size, all patients implanted, N = 965

Implant Location	Valve size (mm)								
	16/19	18/21	20/23	22/25	24/27	26/29	28/31	33	Total
Aortic	15.7	159.3	275.0	255.6	150.1	61.1	7.4	0	924.2
Mitral	0	2.2	4.8	2.4	17.6	99.8	97.7	174.0	398.5
Total	15.7	161.5	279.8	258.0	167.7	160.9	105.1	174.0	1322.7

Table 6: Effectiveness Outcomes, Functional New York Heart (NYHA) Classification

NYHA Class	Pre-op		1 Year (11-14 Months)		2 Year (23-26 Months)		3 Year (35-38 Months)		4 Year (47-50 Months)	
	n/N[1]	%	n/N	%	n/N	%	n/N	%	n/N	%
Aortic Valve Replacement, N = 685										
I	4/685	0.6%	399/431	92.5%	205/231	88.7%	85/94	90.4%	53/58	91.4%
II	267/685	38.9%	25/431	5.8%	20/231	8.7%	7/94	7.4%	5/58	8.6%
III	340/685	49.6%	1/431	0.2%	1/231	0.4%	0/94	0%	0/58	0%
IV	68/685	9.9%	1/431	0.2%	1/231	0.4%	0/94	0%	0/58	0%
Missing	6/685	0.9%	5/431	1.2%	4/231	1.7%	2/94	2.1%	0/58	0%
Mitral Valve Replacement, N = 280										
I	0/280	0%	158/182	86.8%	78/100	78.0%	33/42	78.5%	28/34	82.4%
II	74/280	26.4%	19/182	10.4%	19/100	19.0%	8/42	19.0%	5/34	14.7%
III	155/280	55.4%	3/182	1.6%	2/100	2.0%	1/42	2.4%	1/34	2.9%
IV	45/280	16.1%	0/182	0%	0/100	0%	0/42	0%	0/34	0%
Missing	6/280	2.1%	2/182	1.1%	1/100	1.0%	0/42	0%	0/34	0%

Note:

1. N = all values reported; n = number in subgroup

Table 7: Effectiveness Outcomes – Hemodynamics, Valvular Regurgitation

Valvular Regurgitation	Early[1] % patients, n/N[3]	Late[2] % patients, n/N
Aortic Valve Replacement, N = 685		
No Regurgitation	41.4%, 244/590	34.8%, 119/342
Trivial Regurgitation	57.6%, 340/590	64.6%, 221/342
Mild Regurgitation	1.0%, 6/590	0.6%, 2/342
Moderate Regurgitation	0%, 0/590	0%, 0/342
Severe Regurgitation	0%, 0/590	0%, 0/342
Mitral Valve Replacement, N = 280		
No Regurgitation	60.7%, 128/211	60.5%, 78/129
Trivial Regurgitation	37.4%, 79/211	38.0%, 49/129
Mild Regurgitation	1.9%, 4/211	1.6%, 2/129
Moderate Regurgitation	0%, 0/211	0%, 0/129
Severe Regurgitation	0%, 0/211	0%, 0/129

Notes:

1. Early post-operative evaluation conducted at 30-days post-implantation or hospital discharge.
2. Late post-operative evaluation = 11-14 months post-implantation.
3. N = all values reported; n = number in subgroup

Table 8: Effectiveness Outcomes – Hemodynamics, Mean Pressure Gradient and Effective Orifice Area

Endpoint	Early[1] n/N[3], mean ± SD (min, max)	Late[2] n/N[3], mean ± SD (min, max)
Aortic Valve Replacement, N = 685		
Mean Gradient (mm Hg)		
16/19mm	15/23, 25.8 ± 5.1 (10.5, 49.0)	9/23, 20.2 ± 2.8 (15.0, 26.6)
18/21mm	87/100, 18.7 ± 1.7 (2.4, 42.0)	61/100, 18.0 ± 1.6 (7.0, 36.0)
20/23mm	181/202, 14.3 ± 0.8 (2.6, 37.0)	107/202, 13.1 ± 0.8 (5.1, 30.1)
22/25mm	187/206, 12.8 ± 0.8 (2.6, 29.5)	112/206, 11.1 ± 0.8 (3.2, 26.0)
24/27mm	102/111, 10.0 ± 0.7 (1.8, 22.0)	70/111, 8.0 ± 0.8 (1.3, 16.7)
26/29mm	38/39, 9.2 ± 1.1 (3.5, 18.0)	32/39, 7.8 ± 1.1 (2.0, 13.0)
28/31mm	3/4, 3.0 ± 0.7 (2.6, 3.8)	4/4, 5.1 ± 3.3 (1.4, 9.3)
Effective Orifice Area (cm^2)		
16/19mm	11/23, 1.1 ± 0.2 (0.7, 1.8)	8/23, 1.2 ± 0.3 (0.8, 1.9)
18/21mm	81/100, 1.5 ± 0.1 (0.8, 3.7)	60/100, 1.5 ± 0.1 (0.7, 3.4)
20/23mm	165/202, 1.7 ± 0.1 (0.8, 6.6)	102/202, 1.7 ± 0.1 (0.9, 3.7)
22/25mm	173/206, 2.0 ± 0.1 (1.1, 4.0)	103/206, 2.1 ± 0.1 (1.0, 4.9)
24/27mm	97/111, 2.4 ± 0.2 (1.1, 4.8)	65/111, 2.5 ± 0.2 (1.5, 4.9)
26/29mm	34/39, 3.0 ± 0.3 (1.4, 4.7)	28/39, 3.1 ± 0.4 (1.4, 5.4)
28/31mm	3/4, 2.8 ± 0.8 (2.0, 3.4)	3/4, 3.1 ± 1.6 (1.6, 4.5)

Notes:

1. Early post-operative evaluation conducted at 30-days post implantation or hospital discharge.
2. Late post-operative evaluation = 11-14 months post implantation
3. N= all values reported; n = number in subgroup
4. Echo confirmed valve function.

Table 8: Effectiveness Outcomes – Hemodynamics, Mean Pressure Gradient and Effective Orifice Area - continued

Endpoint	Early[1] n/N[3], mean ± SD (min, max)	Late[2] n/N[3], mean ± SD (min, max)
Mitral Valve Replacement, N = 280		
Mean Gradient (mm Hg)		
16/19mm	0	0
18/21mm	0/3	1/3, 6.0 (6.0, 6.0)
20/23mm	3/5, 5.3 ± 3.6 (3, 9)	4/5, 4.6 ± 0.9 (4.0, 6.0)
22/25mm	1/3, 10.0 (10, 10)	2/3, 5.4 ± 4.7 (3.0, 7.8)
24/27mm	15/23, 4.4 ± 0.9 (2.3, 7.9)	8/23, 4.5 ± 0.9 (2.4, 6.2)
26/29mm	66/71, 3.7 ± 0.4 (1.5, 10.0)	39/71, 3.7 ± 0.7 (1.3, 9.9)
28/31/33mm	154/175, 3.5 ± 0.3 (0.7, 9.0)	106/175, 3.1 ± 0.2 (0.3, 7.3)
Effective Orifice Area (cm^2)		
16/19mm	0	0
18/21mm	0/3	1/3[4]
20/23mm	3/5, 2.9 ± 0.6 (2.3, 3.3)	3/5, 1.6 ± 0.3 (1.3, 1.8)
22/25mm	1/3, 1.6 (1.6, 1.6)	2/3, 1.8 ± 0.5 (1.5, 2.0)
24/27mm	15/23, 3.3 ± 0.5 (1.8, 5.2)	8/23, 2.9 ± 0.9 (1.6, 5.7)
26/29mm	63/71, 3.3 ± 0.2 (1.6, 5.0)	38/71, 2.8 ± 0.3 (1.0, 4.6)
28/31/33mm	140/175, 3.0 ± 0.2 (1.3, 7.6)	95/175, 2.9 ± 0.2 (1.5, 7.4)

Notes:
1. Early post-operative evaluation conducted at 30-days post implantation or hospital discharge.
2. Late post-operative evaluation = 11-14 months post implantation
3. N= all values reported; n = number in subgroup
4. Echo confirmed valve function.

8. INDIVIDUALIZATION OF TREATMENT

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

8.1. Specific Patient Populations

The safety and effectiveness of the ATS Open Pivot® Bileaflet 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.

There was limited use of the valve in patients requiring double or multiple valve replacement.

9. 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 and/or antiplatelet therapy.

- Patients should be encouraged to carry with them at all times a completed Patient ID card provided with the valve.

10. HOW SUPPLIED

10.1. Packaging

The outer carton label serves as a tamper-resistant package seal. ATS Open Pivot® Bileaflet Heart Valves are packaged and steam sterilized in transparent double barrier trays. Examine the trays carefully to verify that the seals and trays are intact. If any seal is damaged or missing, do not use the valve. Each package is supplied sterile with a valve pre-mounted onto a valve holder, a handle/rotator, and a leaflet actuator. The valve, valve holder, handle/rotator, and leaflet actuator in the valve package are ready for use when received unless the package sterility has been compromised or expiration has occurred.

All package labeling and handle/rotator accessories are color-coded and marked: aortic accessories and packaging are GREEN in color; mitral accessories and packaging are RED in color.

The valve sizers (Models 550 and 560) and handles (Model 552) are supplied separately **NON-STERILE**, and must be cleaned and sterilized prior to use.

The valve sizers are available to the implanting surgeon as an aid in selecting the appropriate prosthesis size. Each set of sizers is packaged with instructions for use specific to the sizer.

The actuator is available for testing of valve leaflet motion.

All packaging material is recyclable and should be disposed of accordingly.

10.2. Storage

The ATS Open Pivot® Bileaflet Heart Valve must be stored at room temperature (15°C to 30°C or 59°F to 86°F). The storage life of the ATS Open Pivot® Bileaflet 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.

11. DEVICE IMPLANTATION

11.1. Physician Training

No special training is required to implant the ATS Open Pivot® Bileaflet Heart Valve. The techniques for implanting this valve are similar to those used for any bileaflet mechanical valve.

11.2. Handling and Preparation Instructions

Proper prosthesis size selection is an important part of the heart valve replacement. Size of the ATS Open Pivot® Bileaflet Heart Valve is determined using an ATS sizer (Model 550 or 560).

> **Caution:** The valve accessories (sizer and handle) should not be used unless cleaned and sterilized as per the recommended instructions in Section 11.6.1.

The valve, valve holder, handle/rotator, and leaflet actuator are supplied sterile in the same package (Figures 4, 5, and 6). The contents of the package should be handled in an aseptic manner to prevent contamination.

1) Remove the package from the white shipping box. Verify that the valve size, type, and serial number as marked on the tray label match the information on the white shipping box label. If any differences are noted, do not use the valve for implantation.
2) Examine the lid to verify that the prosthesis container has not been damaged or previously opened. If resterilization of accessories is necessary prior to implantation, follow the recommended cleaning and sterilization guidelines in Section 11.5.
3) Hold the outer tray and gently peel the lid back using sterile techniques until the lid has been completely removed from the tray.
4) Note the valve serial number and size in the operating room log or patient chart. Adhesive-backed chart labels with valve-identifying information, as well as an implant registration card, are included on the bottom of the outer tray. Complete the implant registration card provided and return to ATS Medical or the ATS Medical representative.
5) Remove the inner tray from the outer tray by grasping the inner tray by its lip.
6) Holding the bottom of the inner tray, grasp the inner tray lid tab and peel back until the lid has been completely removed.
7) Using sterile technique, carefully remove the retainer insert and discard.
8) DO NOT REMOVE THE VALVE HOLDER AND HANDLE/ROTATOR ASSEMBLY FROM THE TRAY (Figures 5 and 6) until checking to ensure that the valve holder is secured to the handle/rotator. There should be no visible screw threads at the connection between the colored handle/rotator and the white valve holder when secured properly.
9) Remove the blue leaflet actuator from the tray and set aside for later use.
10) Grasp the handle/rotator in the center and gently lift the valve, valve holder, and handle/rotator out of the inner tray. Do not remove the valve from the valve holder unless instructed by the implanting surgeon.

11.3. Device Implantation

Proper prosthesis size selection is an important part of heart valve replacement. Care must be exercised to avoid using too large or too small of a prosthesis. The size of the prosthesis is determined using the ATS Medical valve sizers. (Figures 7 and 8)

Inspection of the valve should be performed immediately prior to implantation.

Warning: Do not touch the valve (leaflets/orifice) except with the leaflet actuator supplied with the valve. Touching of the valve with gloved fingers or any surgical instrument may cause damage to the valve surface not seen with the unaided eye that may lead to accelerated valve structural deterioration or leaflet escape, or serve as a nidus for thrombus formation.

Caution: Do not use the valve if it has been dropped, damaged, or mishandled in any way. Should the valve be damaged during implantation or removal from the package, do not use for implantation.

Use only ATS Medical accessories for handling of the valve. All accessories should be inspected prior to use. Do NOT use if the surface of any accessory appears damaged or cracked.

11.4. Suturing Techniques

Ensure proper orientation of the valve. The blood flow in either the aortic or mitral position is always into the straight edge of the leaflets. The markers on the sewing cuff (three on the aortic cuff and four on the mitral cuff) are useful in the proper placement of the sutures and orientation of the valve. The aortic markers are 120° apart and may be placed at the approximate location of the commissures of the excised valve. The mitral cuff has four markers 90° apart, which can be placed such that one is at each commissure, one is in the center of the anterior leaflet, and the other is in the center of the posterior leaflet. Further orientation of the valve, if necessary, can be done with the handle/rotator once the valve is seated in the annulus.

Medical practice has evolved numerous acceptable suture methods. The technique used should be based on the patient's anatomy, procedure requirements, and surgeon preference. Pledgets may be used at the discretion of the surgeon for support of the annulus if necessary. Care should be taken to assure that pledgets or tissue do not interfere with leaflet motion. Everting stitches with pledgets would be useful in avoiding situations where tissue might impede leaflet motion.

After sutures are placed in the valve cuff and the valve is seated in the tissue annulus, the valve is released from the valve holder by sliding a scalpel down the holder slot to cut the green suture and release the valve holder. The green suture and valve holder remain attached as the holder and handle/rotator are carefully withdrawn. The suture knots can be tied at this point.

Caution: Long suture ends must be avoided since these can interfere with leaflet motion.

11.4.1. Suturing Technique for Standard Cuffs

Surgeons performing mitral and aortic valve replacements frequently use interrupted everting mattress sutures. Alternatives include interrupted figure of eight sutures or interrupted simple mattress sutures.

11.4.2. Suturing Technique for AP Cuffs

The ATS Open Pivot® Bileaflet Heart Valve AP Models have a supra-annular configuration with less cuff material, so different suture techniques such as horizontal mattress or simple stitch

may be necessary. Deep needle placement will contact the titanium ring inside the sewing cuff, impeding the smooth placement of sutures. Hence sutures should be placed in the outer half of the cuff.

The holder which holds the ATS Open Pivot® Bileaflet Heart Valve AP Model has a small ridge on the ventricular side which protrudes slightly beyond the tissue annulus diameter of the valve. If difficulty is encountered while seating the valve, using the handle /rotator, rock the valve holder assembly back and forth to allow this ridge to pass beyond the tissue annulus. If the difficulty remains, remove the valve from the valve holder/assembly and use the opposite end of the handle/rotator to seat the valve in the annulus.

11.5. Leaflet Motion Assessment and Valve Rotation

Leaflet motion is assessed using the blue leaflet actuator.

Using the blue leaflet actuator, test leaflet motion. If the leaflets do not move freely, the valve orifice may be rotated either clockwise or counterclockwise to a more optimal position. Rotate the orifice only after the suture knots have been tied securing the cuff to the tissue annulus. Use only the appropriate ATS rotators to rotate the valve. The handle/rotator seats properly into the valve orifice when the radial ridge on the handle side of the rotator head (Figures 5 and 6) is aligned with the straight edge of the leaflets. The rotator head is designed to contact the flat surfaces of the orifice near the pivot areas. After rotation of the valve orifice, verify leaflet motion with the blue actuator.

> **Caution:** The valve orifice and leaflets may be rotated *in situ* using only the appropriate ATS Medical handle/rotator. Do NOT use any other instruments for valve rotation.

> **Caution:** If mitral valve apparatus preservation techniques are used, it is important to check leaflet motion following valve implantation.

11.6. Accessories

Sizers

A complete set of ATS Medical sizers (Models 550 and 560) must be cleaned and sterilized prior to surgery and made available in the operating room. Refer to the end of this section for cleaning and sterilization guidelines.

Use only ATS Medical valve sizers to measure the patient's tissue annulus. The ATS Medical valve sizers have a metal shaft that can be shaped allowing the same sizer to be used for mitral or aortic tissue annulus measurement.

The sizer with the diameter marked in millimeters has a clear plastic ring that allows easy tissue annulus measurement. The sizer should pass easily through the patient's tissue annulus with minimal resistance. Do not force the sizer through the tissue annulus. Valve oversizing or undersizing should be avoided.

Caution: Oversizing may cause complications including tissue interference with leaflet motion or improper seating resulting in perivalvular leaks. Oversizing in the aortic position may result in blockage of the coronary ostia. Undersizing may result in increased perivalvular leaks.

Model 550 Standard Valve Sizing – White Handle Sizer

The white handle sizer must be used for sizing of the ATS Open Pivot® Bileaflet Heart Valve Standard model. The same ATS valve sizer set may be used for aortic or mitral sizing for standard valves. The nominal diameter of the sizer in millimeters (mm) is molded into the handle. The sizer selected should pass easily through the patient's annulus without resistance but still provide a snug fit between the sizer ring and tissue annulus.

Model 560 AP Valve Sizing – Blue Handle Sizer

The AP sizers are intended to simulate supra-annular placement of aortic or mitral valves. The blue handle sizer must be used for sizing of the ATS Open Pivot® Bileaflet Heart Valve AP model. The AP valve blue handle sizer has two ring shape sizers. One end of the sizer consists of a cylindrical ring used for measuring the tissue annulus. This end should pass easily through the patient's annulus without resistance, but provide a snug fit. The other sizer end consists of a cylindrical ring (of the same diameter as the opposing ring) with a rounded protruding edge which simulates the supra-annular cuff of the ATS Open Pivot® Bileaflet Heart Valve AP model. This end of the sizer can be fitted into the annulus to allow measurement of both the diameter and height required by the supra-annular ATS Open Pivot® Bileaflet Heart Valve AP model cuff.

The center of the sizer ring is open so that the native annulus beyond the sizer ring can be examined for intruding tissue that might touch the valve leaflets. Any intruding tissue should be removed. If it is not possible to remove intruding tissue or rotate the valve and position the leaflets to avoid leaflet interference, a smaller size AP valve should be selected, sized, and evaluated in the same manner as described above.

Valve Holder and Handle/Rotator

The prosthesis is pre-mounted on a holder (an integral disposable part that is physically mounted to the valve by the manufacturer) and a color-coded handle/rotator (aortic is GREEN and mitral is RED) that is pre-attached to the holder. The rotator is used to rotate the valve *in situ*. The blood flow in either the aortic or mitral position is always into the straight edge of the leaflets.

Valve Handle

The Model 552 handle (Figure 9) can be attached to the holder instead of the handle/rotator assembly during use. The handle has a metal shaft that can be easily shaped to provide access to the aortic or mitral annulus.

11.6.1. Cleaning Recommendations for Accessories

Rinse the accessory with warm tap water for approximately two (2) minutes, brushing the accessory with a soft-bristled cleaning brush to remove all of the grossly visible debris.

Place the accessory for five (5) minutes in an ultrasonic bath containing enzymatic detergent (ENZOL manufactured by Johnson and Johnson, or equivalent enzyme-based, presoak-plus-cleaner for removing tough, dried-on, or hard-to-reach organic matter from instruments) prepared according to the manufacturer's directions. After sonication, scrub the accessories using a cleaning brush to remove any grossly visible debris from all crevices.

Rinse the accessory for fifteen (15) minutes with warm tap water to remove the detergent. Dry and package the accessory for sterilization according to the instructions in Section 11.6.2 for sterilization/resterilization of the accessory.

11.6.2. Sterilization/Resterilization of Accessories

If necessary, the accessories supplied with the valve may be resterilized prior to use. The sterilization/resterilization of accessories (sizer, handle, and leaflet actuator) should be performed according to the following recommended steam sterilization method:

Steam Sterilization	
Time:	minimum: 15 minutes
Temperature:	minimum: 250°F (121°C)
	maximum: 254°F (123°C)

Caution: Do NOT resterilize the valve.

Caution: The holder and handle/rotator must not be sterilized in the tray. Place the accessories inside an autoclave bag for sterilization.

Caution: Extreme care must be exercised when handling the valve holder assembly to avoid structural damage to the valve. Inspect each accessory before each use. Cracked or damaged accessories must not be used.

12. POSTOPERATIVE INFORMATION

12.1. Magnetic Resonance Imaging (MRI) Testing

The ATS Open Pivot® Bileaflet Heart Valve has been shown to be MRI safe when tested using MR systems operating with shielded static magnetic field strengths of 1.5 Tesla or less. However, the testing may cause significant MRI image artifacts or distortion. This phenomenon produces no harmful effects to the patient.

12.2. Returned Product Information

For detailed information on the ATS Medical returned product policy, please contact your local ATS Medical representative.

12.3. Return of Explanted Prosthetic Valves

ATS Medical, Inc. is extremely interested in obtaining recovered clinical specimens of the ATS Open Pivot® Bileaflet Heart Valve. Specific studies of the explant may be performed and a

written report summarizing the findings will be returned to you. Please contact ATS Medical, Inc. to obtain a Returned Material Authorization (RMA). The explanted valve should be placed completely submersed in a 2-5% formalin solution immediately after excision unless otherwise directed by your ATS Medical representative.

13. PATIENT INFORMATION

An *Implant Registration Form* is attached to the bottom of the outer tray. ATS Medical, Inc. requests that all *Implant Registration Forms* be completed at the time of implant and forwarded to your ATS Medical representative or directly to ATS Medical, Inc.

13.1. Implantation Data Card

A *Patient ID Card* is provided with the prosthesis. Patients should be encouraged to carry with them at all times a completed card.

13.2. Patient Information Booklet

ATS Medical, Inc. 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 ATS Medical sales representative.

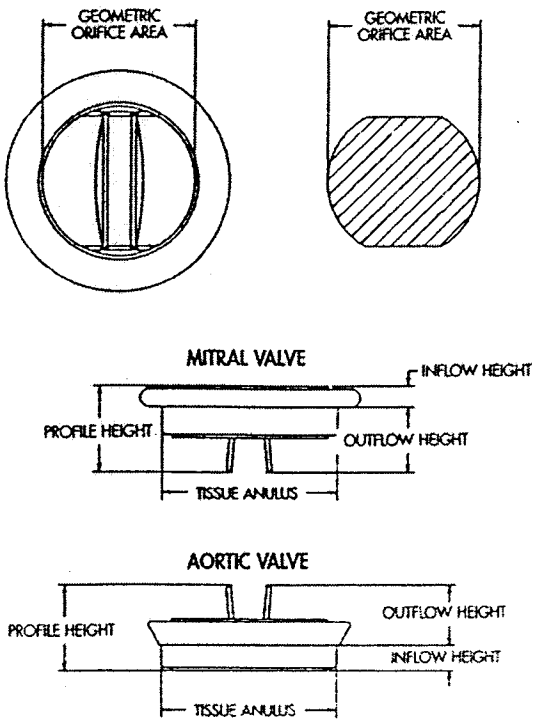


FIGURE 1
Standard DA and FA Valve Aortic & Mitral

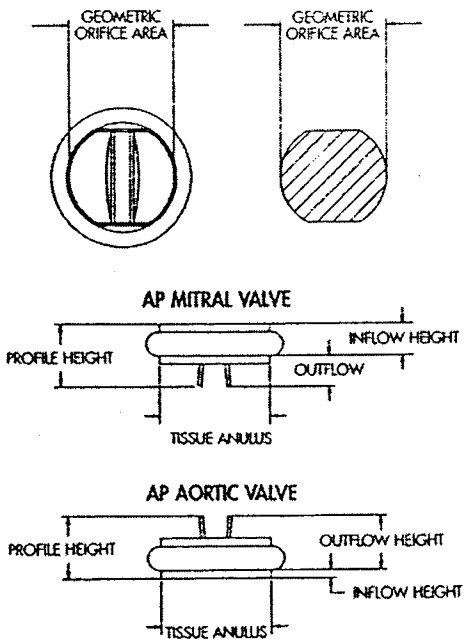


FIGURE 2
Advanced Performance Valve (AP)

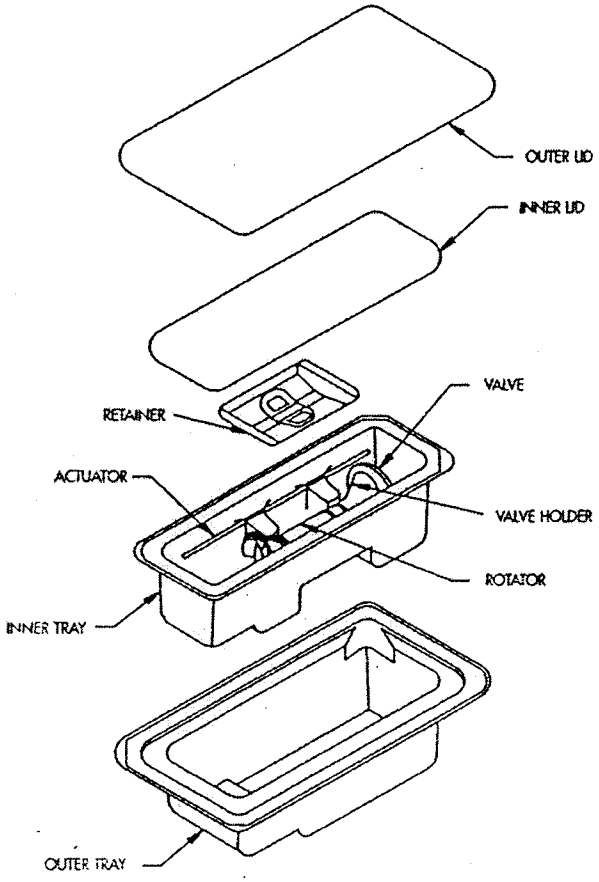


FIGURE 4
Double Barrier Tray Package

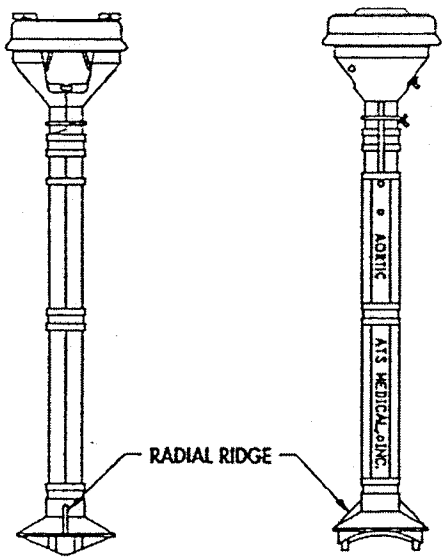


FIGURE 5
Aortic Valve Holder and Handle/Rotator Assembly

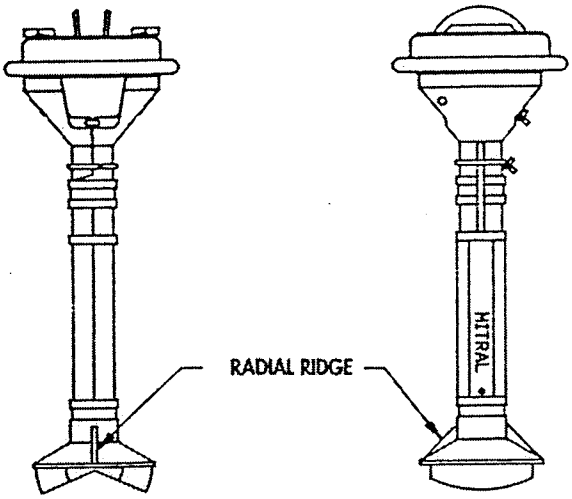


FIGURE 6
Mitral Valve Holder and Handle/Rotator Assembly

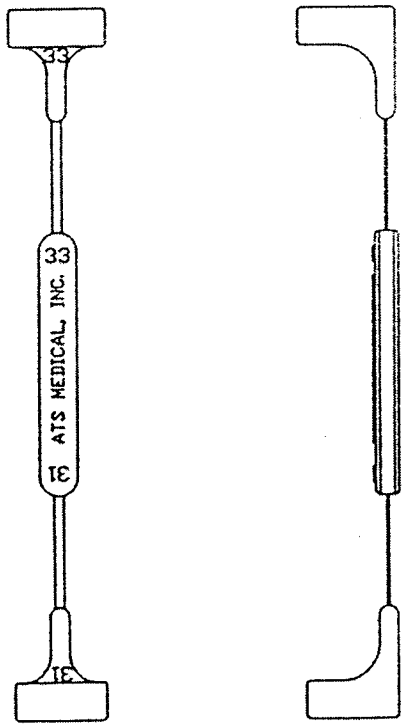


FIGURE 7
Standard Sizer

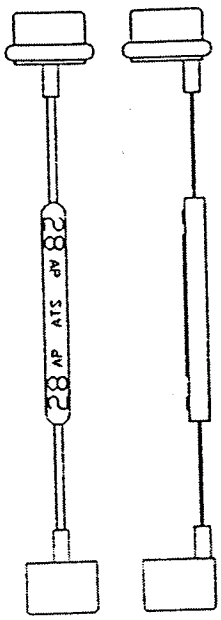


FIGURE 8
AP SIZER

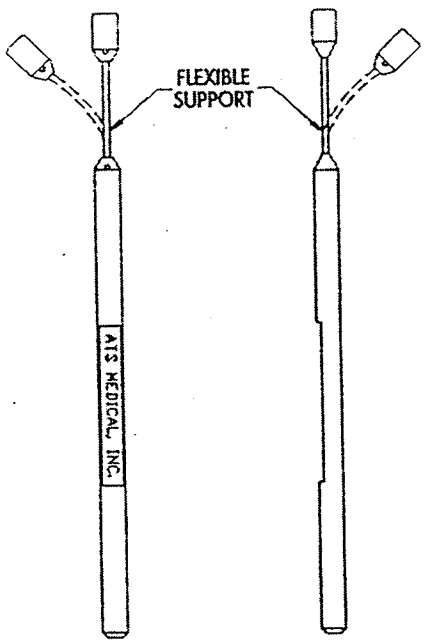


FIGURE 9
Reusable Handle