

INSTRUCTIONS FOR USE

ATS 3f® AORTIC BIOPROSTHESIS, MODEL 1000

CAUTION:

Federal law restricts this device to sale by or on the order of a physician

This device is restricted to use by a physician who has participated in specific implantation training for the ATS 3f® Aortic Bioprosthetic Valve, Model 1000.

The ATS 3f® Aortic Bioprosthetic Valve, Model 1000 is provided Sterile.

The reusable handle and obturator are NOT provided sterile.



1. DEVICE DESCRIPTION

The ATS 3f® Aortic Bioprosthetic Valve, Model 1000 is a stentless pericardial aortic heart valve replacement designed as a tubular structure and constructed from three equal sections of equine pericardium. The equine pericardium is fixed with 0.25% buffered glutaraldehyde to preserve its collagen matrix and reduce its immunogenic and thrombogenic potentials while preserving its strength and flexibility. The proximal orifice of the valve has an attached thin polyester sewing ring used to attach the bioprosthetic valve to the aortic root orifice after resection of the diseased aortic valve. The distal portion of the valve has three commissural tabs, formed from contiguous sections of each of the leaflets and reinforcing polyester material that are used to attach the commissures to the native aortic wall. The device is provided sterile. Final sterilization is achieved with a sterilant formulation based on glutaraldehyde and a low molecular weight alcohol, attaining a sterility assurance level (SAL) of 10^{-6} certified during a quarantine period. The sterilant formulation provides continued germicidal action until the valve is removed from its container. Prior to implantation the device must be rinsed with sterile saline to minimize the tissue glutaraldehyde residuals.

The ATS 3f® Aortic Bioprosthetic Valve, Model 1000 is offered in odd-numbered diameter sizes in increments of 2 mm. Sizes are: 21, 23, 25, 27 and 29 mm.

Table 1: Valve Dimensions

ATS 3f® Aortic Valve Size & Tissue Annulus Diameter ¹ (TAD) [mm]	Valve Height [mm]	Maximum Sinotubular Junction (STJ) Diameter [mm]
A	B	
21	25	25
23	27	27
25	29	29
27	31	31
29	32	33

Figure 1



¹ Tissue Annulus Diameter

The ATS valve sizers provided for the ATS 3f® Aortic Bioprostheses are used to measure the internal diameters of the patient's aortic annulus and sinotubular junction. The aortic valve tissue annulus diameter (TAD) and the sinotubular junction (STJ) diameter determine the correct ATS 3f® Aortic bioprostheses prosthetic size. To ensure proper coaptation the sinotubular junction diameter shall not be greater than 2 sizes (4 mm) more than the tissue annulus diameter. Please refer to the chart above.

2. INDICATIONS FOR USE

The ATS 3f® Aortic Bioprostheses, Model 1000 is indicated for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.

3. CONTRAINDICATIONS

The ATS 3f® Aortic Bioprostheses, Model 1000 should not be used in those patients who present with congenital bicuspid anatomy or other forms of abnormal aortic root geometry.

4. WARNINGS AND PRECAUTIONS

4.1 Warnings

- Accelerated deterioration of the Model 1000 valve due to calcific degeneration may occur in children, adolescents, or young adults, or in patients with altered calcium metabolism such as patients on maintenance hemodialysis for chronic renal failure, patients with hyperparathyroidism, patients on high calcium diets, or patients requiring chronic calcium-containing drug therapy.

4.2 Precautions

- **FOR SINGLE USE ONLY**
- **The ATS 3f Aortic Bioprostheses and gluteraldehyde sterilant storage solution are supplied sterile.**
- **DO NOT RESTERILIZE THE ATS 3f® AORTIC BIOPROSTHESIS, MODEL 1000 BY ANY METHOD.** Exposure of the bioprostheses to radiation, steam, ethylene oxide or other chemical sterilant will render the valve unfit for use.
- **DO NOT FREEZE THE ATS 3f® AORTIC BIOPROSTHESIS, MODEL 1000.** The Model 1000 must be stored in a cool, dry and clean environment with a temperature range between 5°C and 25°C (41°F and 77°F).
- **DO NOT USE IF:**
 - The serial number tag does not match the container label
 - The expiration date has elapsed
 - The seal is broken

- The valve is dropped, or damaged
 - The Freeze Indicator has been activated and escaping dye indicates that the bioprostheses has been exposed to extremes of heat or freezing
- DO NOT expose the bioprostheses to solutions other than the storage and rinsing solutions.
- DO NOT add antibiotics to either the storage solution or the rinse solution.
- DO NOT apply antibiotics to the bioprostheses.
- DO NOT allow the bioprostheses to dry. Keep the bioprostheses moist during surgery with irrigation of saline solution.
- DO NOT use cutting needles; damage to the tissue will occur.
- DO NOT pass instruments, catheters, or transvenous pacing leads through the valve, as damage will occur.

- The performance of the Model 1000 valve is, as is the case for all stentless bioprosthetic valves, dependent on accurate matching of the valve to the recipient patient's aortic annular and sinotubular dimensions and may be adversely affected by high aortic root compliance.
- Recipients of prosthetic heart valves who are undergoing dental or other procedures which are potentially bacteremic should receive prophylactic antibiotic therapy to minimize the possibility of prosthetic valve infection and/or endocarditis.
- Glutaraldehyde may cause irritation of the eyes, nose, skin and throat if continued exposure occurs. Avoid prolonged exposure or breathing of the chemical vapor. Use only with adequate ventilation. If skin contact occurs, flush the affected area copiously (10 – 15 minutes) with water immediately. If eye contact has occurred, flush the eye with water for 15 minutes and seek immediate medical attention.
- The safety and effectiveness of the ATS 3f® Aortic Bioprostheses, Model 1000 has not been established for the following specific populations:
 - Patients who are pregnant
 - Nursing mothers
 - Patients with altered calcium metabolism (e.g., chronic renal failure, hyperparathyroidism)
 - Patients with aneurysmal aortic degenerative conditions (e.g., cystic medial necrosis, Marfan's Syndrome)
 - Patients with active endocarditis
 - Children, adolescents, or young adults

5. ADVERSE EVENTS

5.1 Adverse Events Observed

A prospective, non-randomized, open label, multi-center evaluation of the Safety and Effectiveness of the ATS 3f® Aortic Bioprosthesis, Model 1000 was conducted in Europe and the North America. Data were obtained from valves implanted in 405 patients, assessed at specified intervals with cumulative follow-up of 909.4 patient-years, mean follow-up of 2.3 years (SD = 1.1 years, range of follow-up = 0.01 to 4.4 years). Adverse events, including: thromboembolism, bleeding events (all and major), perivalvular leak (all and major), endocarditis, valve thrombosis, nonstructural dysfunction, structural valve deterioration, hemolysis, mortality (all and valve-related), reoperation and explant were captured during the post operative period and are summarized in the table below:

Table 2: Principal Safety Parameters

All patients analyzed, N=405; Cumulative follow-up = 909.4 patient-years and 876.9 late patient-years

Adverse Event/ Complication	Operative (%)	Linearized Rate (%/Pt-Yr)	Upper 95% Confidence Interval	OPC x 2 (%/Pt-Yr)	Actuarial Analysis at 1 Year Post-op (95% CI)	Actuarial Analysis at 3 Years Post-op (95% CI)
Mortality (All)	3.2	5.1	6.6	N/A	92.1 (89.3,94.9)	83.7 (79.5,87.9)
Mortality (Valve-Related)	0.3	0.3	0.9	N/A	99.2 (98.2,100.0)	98.7 (97.3,100.0)
Reoperation (including Explant)	0.3	0.0	0.0	N/A	99.7 (99.2,100.0)	99.7 (99.2,100.0)
Explant	0.0	1.6	2.5	N/A	98.2 (96.8,99.6)	96.1 (93.9,98.3)
Structural Deterioration	0.0	0.0	0.0	N/A	100.0 (100.0,100.0)	100.0 (100.0,100.0)
Hemolysis	0.0	0.0	0.0	N/A	100.0 (100.0,100.0)	100.0 (100.0,100.0)
Non-Structural Dysfunction	0.5	0.3	0.9	N/A	99.5 (98.7,100.0)	98.6 (97.2,100.0)
Thromboembolism (Valve-Related)	1.7	2.2	3.2	5.0	94.9 (92.7,97.1)	93.2 (90.6,95.8)
Valve Thrombosis	0.0	0.0	0.0	0.4	100.0 (100.0,100.0)	100.0 (100.0,100.0)
Bleeding Events (All)	2.0	1.3	2.1	2.8	96.1 (94.1,98.1)	95.2 (93.0,97.4)
Bleeding Events (Major)	1.7	0.8	1.5	1.8	97.2 (95.6,98.8)	96.5 (94.5,98.5)
Perivalvular leak (All)	1.0	1.0	1.8	2.4	97.7 (96.1,99.3)	96.4 (94.4,98.4)
Perivalvular leak (Major)	0.0	0.3	0.9	1.2	99.2 (98.2,100.0)	99.2 (98.2,100.0)
Endocarditis	0.0	1.0	1.8	2.4	99.2 (98.4,100.0)	97.5 (95.7,99.3)

pt-yr = patient-year; OPC = Objective Performance Criteria as established by the US FDA; CI = Confidence Interval; N/A = not applicable.

5.2 Potential Adverse Events

Adverse events potentially associated with the use of bioprosthetic heart valves include:

- Leak (transvalvular, perivalvular)
 - Cardiac Dysrhythmias
 - Endocarditis
 - Hemolysis
 - Hemorrhage
 - Non-Structural Dysfunction [NSD] (entrapment by pannus or suture, inappropriate sizing or positioning, or other)
 - Structural deterioration (intrinsic and extrinsic calcification, leaflet perforation or tear, leaflet thickening, or myxomatous degeneration)
 - Prosthesis Stenosis
 - Prosthesis Regurgitation
 - Valve Thrombosis
 - Thromboembolism
- It is possible that these complications could lead to:
- Reoperation
 - Explantation
 - Permanent Disability
 - Death

The above complications may present clinically with:

- dyspnea
- orthopnea
- exercise intolerance
- syncope
- fever
- abnormal heart murmur
- anemia (including hemolytic anemia)
- low cardiac output
- pulmonary edema
- heart failure
- angina
- myocardial infarction
- stroke

6. CLINICAL STUDIES

A multicenter non-randomized prospective clinical study was conducted, in which 405 patients were enrolled at fourteen (14) centers in Western Europe and nine (9) centers in North America between October 3, 2001 and December 31, 2005. Patients were evaluated pre-operatively, intra-operatively, at discharge, at 3-6 months, at 1 year, and annually thereafter. The study was designed to evaluate the safety and effectiveness of the ATS 3f® Aortic Bioprostheses, Model 1000 in the subcoronary position.

The safety endpoints captured in this study were mortality and valve-related morbidity. The effectiveness endpoints in this study were New York Heart Association (NYHA) functional

classification and hemodynamic assessments obtained by echocardiography. Patient demographic data and effectiveness data are summarized in the tables below.

Table 3: Pre-operative Clinical Data *

Variable	Category	n	%(n/N) N=397
Age at Implant (Years)	20-29	1	0.3
	30-39	8	2.0
	40-49	11	2.8
	50-59	26	6.6
	60-69	92	23.2
	70-79	197	49.6
	80 & over	62	15.6
Mean Age and Standard Deviation at Implant		70.7 ± 10.5 years	
Gender	Female	158	39.8
	Male	239	60.2
NYHA Classification	I	23	5.8
	II	149	37.5
	III	193	48.6
	IV	32	8.1
Lesion	Stenosis	302	76.1
	Insufficiency	15	3.8
	Mixed	79	19.9
	Prosthesis Dysfunction	1	0.3

* Size 19mm valves were studied but data for this size are not included in this table because of the limited clinical data available at the time of PMA evaluation

Table 4: Operative Clinical Data *

Variable	Category	n	% (n/N) N=397
Etiology of Valvular Dysfunction	Degenerative	329	82.9
	Rheumatic	57	14.4
	Congenital	16	4.0
	Endocarditis	3	0.8
	Other	4	1
Concomitant Procedures	None	251	63.2
	Coronary Artery Bypass	117	29.5
	Mitral Valve Repair or Debridement	8	2
	Myectomy	7	1.8
	Endartectomy	6	1.5
	Aortic Repair	6	1.5
	Maze Procedure	5	1.3
	Concomitant Other	12	3
Previous CV Surgery	None	341	86
	PTCA	24	6.1
	Pacemaker Implant	15	3.8
	Peripheral Vascular Surgery	11	2.8
	Carotid Artery Surgery	8	2.0
	Coronary Artery Bypass	4	1.0
	Abdominal Aortic Aneurysm	1	0.3
	Arrhythmia Surgery (such as ablation)	1	0.3
	Valve Replacement	1	0.3
Heart Valve Size	21 mm	50	12.6
	23 mm	109	27.5
	25 mm	112	28.2
	27 mm	76	19.1
	29 mm	50	12.6

* Size 19mm valves were studied but data for this size are not included in this table because of the limited clinical data available at the time of PMA evaluation.

Table 5: NYHA Functional Classification - Change from Baseline *

Pre-op NYHA Class	1 Year NYHA (N = 327)							
	I		II		III		IV	
	n	%	n	%	n	%	n	%
I	20	6.1	1	0.3	0	0.0	0	0.0
II	73	2.2	47	14.4	5	1.5	0	0.0
III	102	31.2	45	13.8	8	2.4	0	0.0
IV	16	4.9	8	2.4	2	0.6	0	0.0
Total	211	64.5	101	3.1	15	4.6	0	

Pre-op NYHA Class	2 Years NYHA (N = 266)							
	I		II		III		IV	
	n	%	n	%	n	%	n	%
I	17	6.4	1	0.4	0	0.0	0	0.0
II	53	19.9	37	13.4	4	1.5	1	0.4
III	79	29.7	41	15.4	9	3.4	0	0.0
IV	16	6.0	5	1.9	2	0.8	1	0.4
Total	165	62.0	84	31.6	15	5.6	2	0.8

Pre-op NYHA Class	3 Years NYHA (N = 161)							
	I		II		III		IV	
	n	%	n	%	n	%	n	%
I	9	5.6	0	0.0	0		0	0.0
II	32	19.9	12	7.4	2	1.2	0	0.0
III	60	37.3	22	13.7	7	4.3	0	0.0
IV	11	6.8	5	3.7	1	0.6	0	0.0
Total	112	69.6	39	24.2	10	6.2	0	0.0

Pre-op NYHA Class	4 Years NYHA (N = 44)							
	I		II		III		IV	
	N	%	n	%	n	%	n	%
I	3	6.8	1	2.3	0	0.0	0	0.0
II	5	11.4	3	6.8	0	0.0	0	0.0
III	17	38.6	5	11.4	2	4.5	0	0.0
IV	4	9.1	4	9.1	0	0.0	0	0.0
Total	29	65.9	13	29.5	2	4.5	0	0.0

* Size 19mm valves were studied but data for this size are not included in this table because of the limited clinical data available at the time of PMA evaluation.

Table 6: Prevalence and Severity of Aortic Regurgitation*

Interval	N	Severity	21 mm		23 mm		25 mm		27 mm		29 mm	
			n	%	n	%	n	%	n	%	n	%
Discharge	353	0 None/Trace	35	72.9	65	68.4	70	70.0	51	76.1	29	67.4
		1+ Mild	7	14.6	21	22.1	18	18.0	15	22.4	8	18.6
		2+ Moderate	1	2.1	1	1.1	4	4.0	0	0.0	0	0.0
		3+ Moderate/Severe	0	0.0	0	0.0	1	1.0	0	0.0	0	0.0
		4+ Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Regurgitation Not Evaluable	5	10.4	8	8.4	7	7.0	1	1.5	6	14.0
3-6 Months	333	0 None/Trace	29	69.0	58	69.9	72	75.8	53	77.9	34	75.5
		1+ Mild	12	28.6	20	24.1	17	17.9	13	19.1	9	20.0
		2+ Moderate	1	2.4	4	4.8	3	3.2	0	0.0	2	4.4
		3+ Moderate/Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		4+ Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Regurgitation Not Evaluable	0	0.0	1	1.2	3	3.2	2	2.9	0	0.0
1 Year	328	0 None/Trace	33	80.5	60	73.2	69	76.7	51	75.0	34	72.3
		1+ Mild	8	19.5	18	22.0	18	20.0	14	20.6	9	19.1
		2+ Moderate	0	0.0	2	2.4	3	3.3	2	2.9	2	4.3
		3+ Moderate/Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		4+ Severe	0	0.0	0	0.0	0	0.0	0	0.0	1	2.1
		Regurgitation Not Evaluable	0	0.0	2	2.4	0	0.0	1	1.5	1	2.1
2 Years	258	0 None/Trace	24	80.0	43	70.5	49	72.1	41	70.7	25	61.0
		1+ Mild	4	13.3	9	14.8	13	19.1	13	22.4	11	26.8
		2+ Moderate	0	0.0	4	6.6	5	7.4	3	5.2	2	4.9
		3+ Moderate/Severe	0	0.0	0	0.0	0	0.0	0	0.0	1	2.4
		4+ Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Regurgitation Not Evaluable	2	6.7	5	8.2	1	1.5	1	1.7	2	4.9

Interval	N	Severity	21 mm		23 mm		25 mm		27 mm		29 mm	
			n	%	n	%	n	%	n	%	n	%
3 Years	146	0 None/Trace	12	66.7	23	65.7	27	75.0	20	69.0	19	67.9
		1+ Mild	5	27.8	7	20.0	4	11.1	5	17.2	3	10.7
		2+ Moderate	1	5.6	1	2.9	1	2.8	0	0.0	4	14.3
		3+ Moderate/Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		4+ Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
4 Years	37	0 None/Trace	3	75.0	1	25.0	6	66.7	8	66.7	6	75.0
		1+ Mild	1	25.0	1	25.0	2	22.2	2	16.7	2	25.0
		2+ Moderate	0	0.0		10.0	1	11.1	2	16.7	0	0.0
		3+ Moderate/Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		4+ Severe	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
		Regurgitation Not Evaluable	0	0.0	4	11.4	4	11.1	4	13.8	2	7.1

* Size 19mm valves were studied but data for this size are not included in this table because of the limited clinical data available at the time of PMA evaluation.

Table 7: Hemodynamic Data by Valve Size*

Visit	Variable	Valve Size											
		21 mm				23 mm				25 mm			
		Total N	Mean	Std	N	Mean	Std	N	Mean	Std	N	Mean	Std
Discharge	Mean Gradient (mm Hg)	323 46	16.2	7.1	83	15.8	7.0	94	12.5	5.0	61	10.4	5.0
	Peak Gradient (mm Hg)	323 46	29.1	11.9	83	28.5	12.9	94	22.8	9.1	61	19.0	8.9
	EOA (cm ²)	240 31	1.3	0.4	57	1.3	0.4	75	1.6	0.4	49	1.9	0.5
3-6 Months	Mean Gradient (mm Hg)	320 39	15.0	4.6	79	14.5	6.0	92	11.4	4.0	65	9.4	3.3
	Peak Gradient (mm Hg)	320 39	27.0	8.4	79	25.7	10.8	92	20.3	7.4	65	16.8	6.3
	EOA (cm ²)	245 32	1.1	0.4	59	1.4	0.4	68	1.6	0.5	51	1.9	0.5
1 Year	Mean Gradient (mm Hg)	312 41	16.4	5.5	76	14.8	6.0	89	11.5	4.8	62	10.3	4.4
	Peak Gradient (mm Hg)	312 41	28.4	9.4	76	25.4	9.7	89	20.3	8.1	62	18.6	7.8
	EOA (cm ²)	248 28	1.2	0.3	56	1.3	0.3	69	1.6	0.4	56	1.9	0.5
2 Years	Mean Gradient (mm Hg)	247 29	15.4	5.3	59	14.0	5.6	66	11.3	4.2	55	9.1	3.7
	Peak Gradient (mm Hg)	247 29	27.0	9.2	59	24.4	9.2	66	20.1	7.5	55	16.7	6.8
	EOA (cm ²)	171 15	1.1	0.4	38	1.3	0.3	49	1.6	0.5	40	1.9	0.5
3 Years	Mean Gradient (mm Hg)	138 17	15.6	5.9	29	14.2	5.9	33	10.4	5.0	30	8.9	3.7
	Peak Gradient (mm Hg)	138 17	29.2	9.4	29	25.2	10.6	33	18.9	9.1	30	16.6	6.9
	EOA (cm ²)	96 12	1.0	0.3	18	1.2	0.4	25	1.6	0.5	20	1.9	0.5
4 Years	Mean Gradient (mm Hg)	34 3	11.0	2.6	4	15.0	7.1	9	9.7	4.4	10	9.6	2.5
	Peak Gradient (mm Hg)	34 3	20.3	5.5	4	26.3	12.3	9	18.1	8.7	10	18.6	5.3
	EOA (cm ²)	25 1	0.9	·	1	0.9	·	6	1.4	0.4	10	1.6	0.4

* Size 19mm valves were studied but data for this size are not included in this table because of the limited clinical data available at the time of PMA evaluation.

7. PATIENT COUNSELING INFORMATION

The physician should determine the best anticoagulant regimen for each patient receiving the ATS 3f® Aortic Bioprostheses, Model 1000. Unless specifically contraindicated, it is recommended that bioprosthetic heart valve recipients should be maintained on anticoagulant therapy for 12 weeks following the surgery. Anticoagulants should then be discontinued gradually, unless long-term anticoagulation is indicated because of risk factors for thromboembolism. Long-term therapy with low dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves..

Recipients of prosthetic heart valves who are undergoing dental or other procedures which are potentially bacteremic should receive prophylactic antibiotic therapy to minimize the possibility of prosthetic valve infection and/or endocarditis.

Patients should be encouraged to carry the Implanted Device Identification Card, provided by ATS Medical, Inc., with them at all times.

8. HOW SUPPLIED

9.1 Packaging

The ATS 3f® Aortic Bioprostheses, Model 1000 is supplied STERILE in a 1% buffered glutaraldehyde solution. Sterility is assured if the tamper-evident label is undamaged.

9.2 Storage

The Model 1000 must be stored in a cool, dry and clean environment. Storage temperature must range between 5°C and 25°C (41°F and 77°F). The storage life of the device is indicated by the "Use By" date on the outer package labeling. Appropriate inventory control should be maintained so that the bioprostheses with earlier "Use By" dates are preferentially implanted. Refrigeration is not required and freezing will damage the bioprostheses.

10. DIRECTIONS FOR USE

10.1 Physician Training

This device is restricted to use by a physician who has participated in specific implantation training for the ATS 3f® Aortic Bioprostheses, Model 1000. The function of a stentless bioprosthetic valve is sensitive to surgical implantation technique. Implanting physicians must be familiar with the techniques for implanting a stentless bioprostheses in

the subcoronary position. These techniques are similar to those required for allograft implantation.

10.2 Handling and Preparation Instructions

Caution: The ATS 3f® Aortic Bioprostheses, Model 1000 and glutaraldehyde sterilant storage solution are supplied sterile. The outside of the jar is not sterile.

Bioprostheses size selection is an important part of valve replacement. Use only ATS obturator to select the appropriate size of the ATS 3f® Aortic Bioprostheses, Model 1000.

Prepare a total of four (4) sterile bowls, each containing 500 ml of sterile saline solution to remove the sterilant from the valve.

The valve is packaged sterile in a plastic jar with a screw-cap closure and seal. The exterior of the device container and the screw-cap are non-sterile. Before opening, carefully examine the seal to verify that the container has not been damaged or previously opened. Remove the seal and turn the jar cap counter-clockwise to open the container.

After opening the container, inspect the level of storage solution in the jar. The jar should contain enough buffered glutaraldehyde storage solution to completely cover the bioprostheses. If it does not, DO NOT USE the valve. The contents of the jar should be handled in an aseptic manner to prevent contamination.

A serial number tag is attached to the holder of each valve with a loose suture. This serial number should be checked against the number on the jar container and implantation data card; if any differences are noted, the valve should be returned unused. This tag should not be detached from the valve until implant is imminent. Care should be exercised during removal of the tag to insure that no damage is done to the leaflet tissue.

Attach the reusable handle to the disposable valve holder assembly by inserting the threaded end of the handle into the threaded orifice in the center of the valve holder. Rotate the handle clockwise into the valve holder until it will no longer rotate and is secure. This will keep the assembly attached to the handle as it is removed from the container.

Once the handle is securely attached to the valve holder, it should not be disengaged until all annular sutures are placed into the sewing ring.

Using sterile technique, carefully remove the assembly from the container making sure not to touch the external, non-sterile, surfaces of the container. Lift and slide the attached valve holder and valve through the slit of the retainer. Inspect the valve and immediately place the assembly into the first of the four bowls of sterile saline.

10.3 Rinse Procedure

Carefully swirl the valve through the solution from side to side for a minimum of **30 seconds** in the first rinsing bowl. Be sure the saline solution completely covers the bioprosthesis and holder. Repeat this rinsing procedure in the second bowl of sterile saline for an additional **30 seconds** and then repeat again in the third bowl of sterile saline for another **30 seconds**.

After the valve has been rinsed, it is ready for implantation. The valve should be left in the fourth bowl until required by the surgeon.

Caution: Do not add antibiotics to either the storage solution or the rinse solution. Do not apply antibiotics to the valve.

No other objects should be placed in the rinse bowl.

10.4 Surgical Precautions

- Inspect the valve and remove the identification tag prior to implantation.
- Use only the obturators supplied by ATS for the ATS 3f® Aortic Bioprostheses, Model 1000 to size the patient. Use of other manufacturer's obturators may result in an oversized or undersized valve being selected and implanted. Do not oversize, as oversizing will result in excessive material within the outflow track resulting in obstruction and suboptimal hemodynamic performance of the valve.
- The sutures used to secure the ATS 3f® Aortic Bioprostheses, Model 1000 sewing ring to the native aortic annulus must be carefully spaced to avoid distortion of the aortic prosthetic valve leaflets or the native aortic wall.
- An interrupted suture technique is recommended for implantation of the ATS 3f® Aortic Bioprostheses, Model 1000. Cut the suture tails to avoid contact with the leaflets.
- Gentle handling is required for all implantable devices. If the valve is dropped, damaged or mishandled in any way, it must not be used for human implantation.

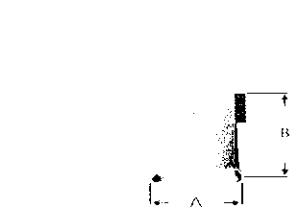
10.5 Surgical Procedure

The following steps are recommended once full exposure of the aorta and cardiopulmonary bypass is instituted:

Aortotomy - A horizontal aortotomy with partial or complete transection of the aorta should be placed above the sinotubular junction (STJ, aortic cristae) such that it is greater than the valve height as depicted in **Table 8** and **Figure 3**. It is essential to place the aortotomy at least this far above the STJ to ensure ample space for attachment of the three commissural tabs to the aortic wall below the site of the aortotomy.

Figure 3

Table 8



¹ Tissue Annulus Diameter

ATS 3f® Aortic Valve Size & Tissue Annulus Diameter ¹ (TAD) [mm]	Valve Height [mm]
A	B
21	25
23	27
25	29
27	31
29	32

CAUTION: Longitudinal, oblique or “hockey-stick” incisions are to be STRICTLY AVOIDED because such incisions may interfere with the accurate positioning of the commissural tabs at 120-degree intervals within the lumen of the ascending aorta which could lead to severe hemodynamic dysfunction of the implanted valve. Similarly, the presence of any significant abnormal aortic root geometry is a contraindication for implantation of the ATS 3f® Aortic Bioprosthetic Valve, Model 1000. Resect the diseased or damaged valve and appropriately debride the remaining aortic valve annulus of calcium and/or other disease processes (abscess, necrotic material, etc.).

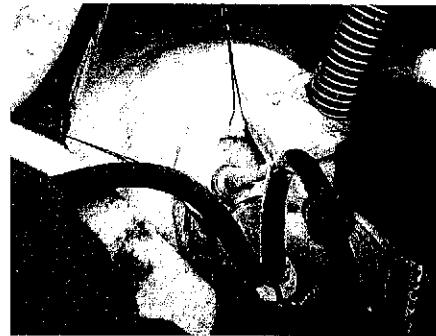
Figure 4



Measure the diameter of the aortic valve annulus using only ATS sizing obturators for the ATS 3f® Aortic Bioprosthetic Valve, Model 1000. If some resistance is met when passing the obturator through the aortic valve annulus, the **immediate smaller size valve should be chosen. Oversizing must be avoided or hemodynamic dysfunction of the implanted valve may result.**

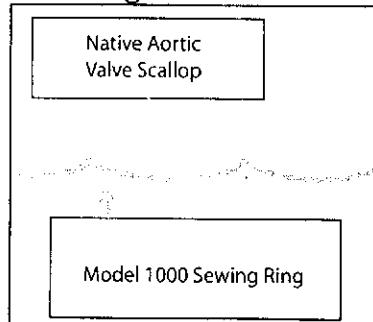
To ensure proper coaptation the sinotubular junction diameter shall not be greater than 2 sizes (4 mm) more than the tissue annulus diameter (TAD).

Figure 5



Suture Technique - An interrupted suture technique is recommended for implantation of the ATS 3f® Aortic Bioprosthetic Valve, Model 1000. Braided suture is recommended for the annular sutures. Cut suture tails close to the knots to avoid contact with the valve leaflets during systole. The inflow suture line should follow a quasi-planar suture line, such as the one used to implant aortic homografts (See **Figure 6** below).

Figure 6



During the implantation, the valve should be periodically irrigated with sterile saline to prevent drying of the valve tissue.

After the interrupted sutures have been placed through the native aortic annulus and the bioprosthetic sewing ring, the prosthesis should be positioned closer to the level of the native aortic annulus. Gently remove the outer valve holder by cutting the three retaining sutures located on the top of each post and the green suture located on the top of the outer valve holder (See **Figure 7** below).

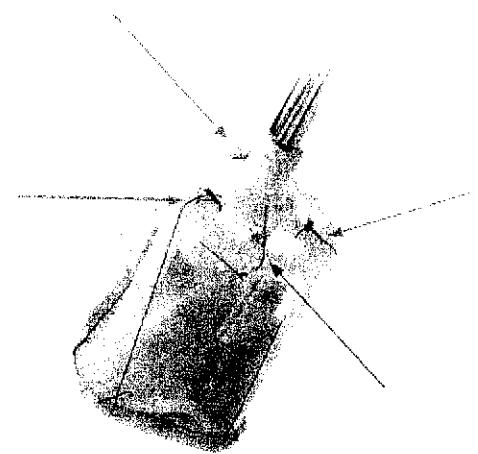


Figure 7

After cutting the retaining sutures, hold the valve in place and gently pull the handle until the retaining sutures pull free from the valve. The handle should then be unscrewed from the holder and the holder discarded.

Secure the prosthetic valve in position by tying the individual sutures using standard surgical technique.

The suture tails should be cut close to the knot to avoid contact of the suture tails with the valve leaflets during systole.

Commissural Tab Attachment - Once the bioprosthesis is secured at the level of the aortic annulus, the three commissural tabs must be affixed to the wall of the aorta. There are two requirements that must be met in order to attach the commissural tabs in the correct position on the aortic wall. First, the tabs must be placed at the correct height above the inflow suture line and secondly the tabs must be spaced at 120 degrees from one another within the lumen of the aorta.

Positioning the Commissural Tabs at the Correct Height:

To properly position the three commissural tabs within the aorta at the correct height, gently retract the central post of the inner valve holder using a surgical clamp or fingers, without introducing any torsion of the valve. While simultaneously placing gentle tension on the aorta, pull the holder upward while being certain that the vertical suture lines between the leaflets of the prosthesis are kept straight. The simultaneous gentle traction on both the prosthesis and the native aorta ensures that there is no "sagging" of the aortic wall and the tabs are attached at the correct height from the inflow suture line.

Spacing the Commissural Tabs at 120-Degree Intervals:

The inner valve holder keeps the three tabs 120 degrees apart and ensures that each tab is spaced properly during commissural tabs attachment to the lumen of the aorta.

Fixation Technique for the Commissural Tabs:

To affix each tab to the aortic wall, use three (3) separate mattress sutures with pledgets: two (2) lateral sutures and one (1) horizontal suture (See **Figure 8** below).

- 1) Each tab should be affixed to the aorta, with two vertical stitches, prior to removal of the inner holder.

The inner holder should be removed by cutting the blue assembly suture in two places (See **Figure 9** below) and gently pulling the inner valve holder from each tab of the valve.

- 2) Once the inner holder has been removed, the final horizontal suture can be placed to complete the tab fixation.
- 3) The tabs are then secured to the aortic wall using external pledgets and standard surgical techniques.

The use of all three sutures prevents the stasis of blood behind the commissural tabs reducing the likelihood of thromboembolic events.

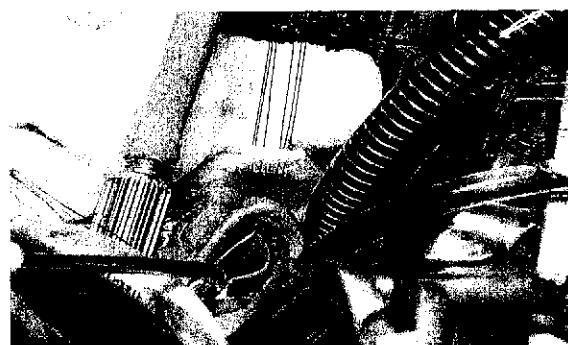


Figure 8

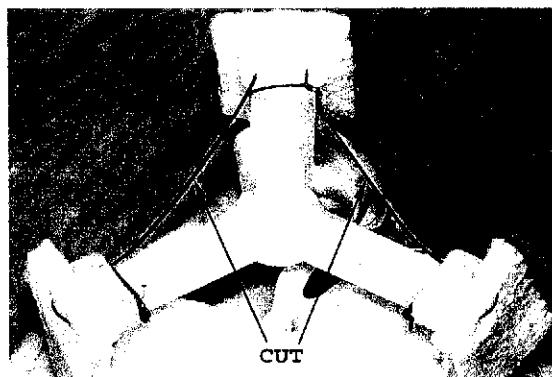


Figure 9

Closing the Aortotomy - Close the aortotomy, taking care to avoid creating any torsion of the ascending aorta which could result in dysfunction.

10.6 Accessories

Obturators - Obturators for each size valve are available for use with the ATS 3f® Aortic Bioprostheses, Model 1000. The sizing obturators are designed to permit direct confirmation of their fit within the annulus.

Disposable Valve Holder Assembly and Reusable Handle - The disposable valve holder attached to the valve consists of two parts:

- 1) the outer holder which is attached to the inflow of the valve, and
- 2) the inner holder which is attached to the outflow tabs of the valve

A reusable handle is provided and attaches to the disposable valve holder to aid in valve removal from the container and valve implantation.

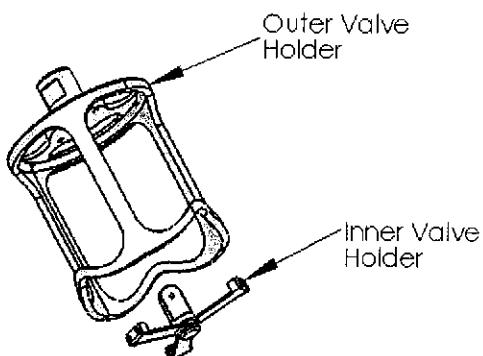


Figure 10

Steam Sterilization of Reusable Handles and Obturators - Reusable handles and obturators are supplied non-sterile and must be cleaned and sterilized before each use.

The following conditions are recommended:

Autoclave Cycle:

132°C [270°F] for 30 minutes

Each institution should employ procedures that include biological indicators to determine the effectiveness of the sterilization procedure.

11.0 POSTOPERATIVE INFORMATION

11.1 Magnetic Resonance Imaging (MRI) Compatibility

The ATS 3f® Aortic Bioprosthetic Valve, Model 1000 is made of nonferrous or nonferromagnetic metallic materials and is considered MRI Safe.

There are no hazardous bioeffects or safety concerns for patients undergoing MRI with an implanted ATS 3f® Aortic Bioprosthetic Valve, Model 1000; MRI emissions do not affect the ATS 3f® Aortic Bioprosthetic Valve, Model 1000 and the function of the valve is not impeded during a procedure involving the proper use of the MRI equipment.

11.2 Recovered Clinical Valves

ATS Medical is interested in obtaining recovered clinical specimens of the ATS 3f® Aortic Bioprosthetic Valve, Model 1000 valves for analysis. A written report summarizing our findings will be provided upon completion of our evaluation, if requested. The explanted valves should be placed into a suitable histological fixative, such as 10% formalin or 2% glutaraldehyde and returned to ATS Medical. Refrigeration is not necessary under these circumstances. Contact ATS Medical to request for an Explant Valve Kit.

12. PATIENT REGISTRATION CARD

12.1 Registration Information

This form is included in each device package. The patient implant card with write-on surface is to be completed after implantation. Please complete all requested information. An Implanted Device Identification Card is provided to the patient. The card contains the name and telephone number of the patient's physician, and information that medical personnel would require in the event of an emergency.

12.2 Patient Manual

Patient Information materials may be obtained from ATS Medical or an ATS Medical clinical sales specialist. A copy should be provided to each patient.

13. DISCLAIMER OF WARRANTY

The following disclaimer of warranty applies to customers outside the United States:

Although the ATS 3f® Aortic Bioprosthetic Valve, Model 1000, hereafter referred to as "product" has been carefully designed, manufactured and tested, ATS Medical has no control over the conditions under which this product is used. ATS Medical, therefore disclaims all warranties, both express and implied, with respect to the product, including but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ATS Medical shall not be liable to any person or entity for any medical expenses or any direct,

incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind ATS Medical to any representation or warranty with respect to the product.

SYMBOL PURPOSE



See Instructions for Use



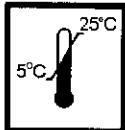
For Single Use Only



Use By

STERILE | **LC**

Device has been sterilized using Liquid Chemical Sterilant according to EN/ISO 14160



Storage Temperature



Size: Diameter of valve inflow end

SN

Serial Number

REF

Catalog/Model Number



Manufacturer



Authorized Representative in the European Community



MR Safe



ATS Medical, Inc.
20412 James Bay Circle
Lake Forest, CA USA 92630
Phone: +01 949 380 9333
Fax: +01 949 380 9399



MedDARE Sarl, 136 Route de Geneve 74240 Gaillard, France
Toll Free Tel: 00800 9 2500 853
Tel: 00 32 9 2500 145
Fax: 00 32 9 2611 535

U.S. Pat. Nos. 6,092,529; Pat. 6,270,526; Pat. 6,682,559 ; Pat. 6,673,109 ; Pat. 6,719,787 ;
Pat. 6,719,788 ; Pat. 6,719,789 ;
Aust. Pat. 726577 ; NZ Pat. 502695.
Other patents are pending.

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LIVING WITH YOUR ATS 3f® AORTIC BIOPROTHESIS

PATIENT INFORMATION

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Each year, an increasing number of people need treatment for heart valve disease.

The purpose of this booklet is to help you learn more about heart valves and treatment options for people with heart valve problems. This booklet is a place for you to begin learning about heart valve disease and the use of replacement heart valves.

You are the most important person in your health care team. Your cardiologist and cardiac surgeon are the most qualified persons to answer your questions about heart valve disease. ATS Medical encourages you to ask questions and to become informed about your medical procedure. This booklet is not intended to replace the advice or instructions from your health care providers.

GLOSSARY

Anticoagulation: Medications that interfere with, or inhibit, blood from clotting are sometimes recommended for patients with atrial fibrillation or an artificial valve. An example of a weak or mild anticoagulant is aspirin. An example of a more powerful anticoagulant is warfarin or coumadin.

Bacterial endocarditis: Occasionally a blood stream infection will settle on a heart valve and damage it. The infection is called bacterial endocarditis.

Biological valves: Artificial valves made from humans or animals, rather than from metal, are called biological valves.

Cardiac catheterization: Cardiac catheterization is a procedure accomplished by passing small tubes or catheters into the heart from arteries and veins in the groin or arm. It is performed by a cardiologist with specialized training. Many conditions affecting the heart require direct measurement of pressures in the chambers or injection of dye (contrast material visible on X-ray).

Cardiac surgeon: Cardiac or cardiothoracic surgeons are surgeons who undergo specialized training in surgery of the heart, lungs, esophagus and other contents of the chest. In the United States, board certified cardiothoracic surgeons have successfully completed a five-year residency in general surgery and have passed their board certification exam in general surgery. The training in cardiothoracic surgery requires two or three additional years of residency after general surgical training.

Cardiologist: Cardiologists are physicians trained in Internal Medicine who specialize in diseases of the heart.

Echocardiogram (ECHO): An ECHO is a sound wave picture of the heart that gives information about the valves of the heart and the function of the muscular walls of the heart.

Electrocardiogram: The electrocardiogram is a test of the way the electrical impulses flow through the heart. Abnormalities may indicate that a heart attack has occurred in the past.

Equine: Derived from a horse.

Ischemic: This term means not having enough blood flow. When a part of the body does not receive enough blood flow, it is called ischemic.

Prosthesis: An artificial replacement part, such as an artificial valve, is called a prosthesis.

Pericardium: A tissue sac that encloses the heart.

Regurgitation: When a heart valve leaks it is said to be "regurgitant," or to exhibit regurgitation.

Rheumatic fever: Streptococcal infection occasionally causes a more generalized disease or inflammation in the joints and heart valves. In heart valves, this may progress with time to ultimately damage the valves sufficiently enough that they must be replaced. This is called rheumatic heart disease.

Stenosis: Narrowing of a heart valve or an artery is called stenosis. A stenotic valve does not open completely and therefore it obstructs or blocks blood from moving through it normally.

VALVE DESCRIPTION

Indications for Use

The ATS 3f® Aortic Bioprostheses (or Heart Valve) is intended for the replacement of diseased, damaged or malfunctioning aortic heart valves. ATS 3f® Heart Valves must be prescribed and ordered by a licensed physician.

Description

The ATS 3f® Heart Valve is made from equine pericardium, which is tissue harvested from a horse and processed for human use. The valve is assembled into a tubular shape, and one end is covered with a fabric ring. This fabric ring is used to sew or attach the valve to a patient's heart tissues.

Contraindications

The ATS 3f® Aortic Bioprostheses, Model 1000 should not be used in patients who have an abnormally shaped heart valve (e.g., congenital bicuspid anatomy or other forms of abnormal aortic root geometry). The ATS 3f® Aortic Bioprostheses, Model 1000 is only approved for replacement of the aortic heart valve.

Before Surgery

Preparation for valve replacement surgery is similar to preparation for other major surgeries. You will be asked to not eat anything for up to 12 hours before surgery to prevent the risk of vomiting while you are under anesthesia. Your doctor may also have you stop or start taking certain medications temporarily.

Surgery

In the operating room, a number of monitoring devices, such as an EKG, to monitor the function of your heart and other vital signs during surgery will be attached to your body and an intravenous (IV) line will be inserted into your arm to deliver fluids and any necessary medication. To help you breathe during surgery, you will be placed on a respirator, which involves placing a tube down your throat and into your lungs.

You will be placed under general anesthesia so that you do not see or feel anything during surgery. After you are unconscious, a transesophageal echocardiogram, which is a type of ultrasound device, will be inserted into your esophagus to display images of your heart during surgery.

To gain access to the heart, the surgeon must cut through your sternum, or breastbone.

Once your heart is visible, the surgeon will place you on a heart-lung machine, which will take over the function of your heart and lungs for the remainder of the

operation by circulating oxygen-rich blood throughout your body. During this bypass, your aorta is clamped near your valve to prevent blood from interfering with the surgery. This bypass is necessary because it is difficult to work on your heart while it is beating.

Once blood flow is diverted to the heart-lung machine, the surgeon will make an incision in the aorta to expose the aortic valve. After the old valve is removed, the surgeon will use a device to measure the size of the valve opening to select the largest possible size for the replacement valve to ensure the best possible blood flow through the valve.

When the new valve is in place, the surgeon will allow some blood to flow through the valve to check for leaks and allow your heart to start beating again. When your heart is beating normally, your surgeon will close your rib cage using heavy-gauge steel wire to sew the breastbone (sternum) together and use stitches to close the incision in your chest. In most cases, you will have a visible scar on your chest. The entire operation generally lasts 2 to 5 hours.

After Surgery

After surgery, you will be taken to an intensive care unit (ICU) in the hospital where your recovery can be monitored closely. The breathing tube usually will be removed from your lungs soon after you wake up. You will probably have a tube in your chest for the next couple of days to remove excess fluids while your chest heals. You will be encouraged to return to your normal daily routines, with advice from your health care team. Your doctor will prescribe a program for your recovery that includes diet, exercise and medications.

Risks and benefits

All prosthetic heart valve implant surgeries carry some risks of complications, but the use of the ATS 3f® Aortic Bioprostheses, does not carry any increased risk over those of other bioprosthetic heart valves on the market today. Heart valve replacement surgery is generally considered safe, and you should begin to feel better almost immediately. However, risks and complications are possible. Some of the potential complications include, blood clot formation, infection, bleeding, stroke and heart failure.

Despite, the risks associated to the surgery, it is also important to consider the benefits of the surgery improving your quality of life and chances of survival.

Ask your physician if you have any questions about potential risks or if you have more questions about heart valve replacement.

Magnetic Resonance Imaging (MRI)

In the event that your physician recommends a MRI test for you, the ATS 3f® Heart Valve is safe to be imaged.

Traveling

The ATS 3f® Heart Valve will not cause airport security alarms to sound. However, it is always a good idea when traveling to carry your patient identification card with you.

A Reminder from ATS Medical...

Remember that you are the primary member of your health care team! Report any problems to your physician, take your medications as prescribed, and ask questions if you don't understand any health related instructions from your care providers.

THE HUMAN HEART

Your heart is a strong muscular organ. It is the main pump in your blood system. Blood pumped by your heart carries oxygen and energy to your brain, muscles and organs. Each human heart is made up of four unique chambers, separated by four individual heart valves. The heart's pumping actions are made more efficient by these valves that open and close with each heart beat.

The four human heart valves are tissue flaps designed to allow one-way movement of blood through the heart's four chambers. Healthy heart valves open fully to let blood flow forward into the next chamber. The valves then close to prevent blood from flowing backward. Healthy heart valves keep blood flowing correctly through the heart. When heart valves are defective, the heart has to work harder to move blood through the body.

People with valve disease may have one or more of the following symptoms:

- Problems breathing with mild exertion or while resting
- Wheezing or coughing during exercise
- A sensation of fluttering or fast pounding in the chest
- Easily tired
- Dizzy spells or fainting
- Swelling in the ankles or hands
- Pressure or pain in the chest
- Physician-diagnosed heart "murmur"

Your doctor may prescribe a series of tests to diagnose the type of heart valve disease you have. These tests may include a chest X-ray, an echocardiogram, an

electrocardiogram and/or cardiac catheterization.

HEART VALVE DISEASE

When you listen to your own heart beat, you hear the familiar two-part sound often described as “lub-dub.” This sound is caused by the opening and closing of the heart valves. A human heart beats more than 100,000 times each day, requiring the heart valves to open and close nearly one million times per week!

Heart valve disease is diagnosed when valves fail to open and close properly. If your heart valve is damaged or defective, you may have an extra sound in your heart called a heart “murmur.” This sound is caused by blood moving abnormally across your heart valve. Not all heart murmurs require medical treatment.

There are several causes of heart valve disease. Some people are born with defective valves. A minor defect can progress over time to be a condition that requires treatment. Diseases such as rheumatic fever and bacterial endocarditis can damage heart valves, causing scarring. The aging process and coronary artery disease can also cause heart valve problems. Many people lead normal lives despite their heart valve disease. Medical treatment with drugs, and lifestyle changes, may be enough to treat your heart valve problems. Your doctor will discuss these options with you.

Valves that no longer open fully are diagnosed as “stenotic” valves. Valve stenosis can be caused by an infection or by aged tissues that become less flexible over time. This process begins to block, or restrict, blood flow across the valve area. A heart valve with stenosis does not allow enough blood to flow through to other heart chambers or to the body.

Valves that open easily but fail to close tightly are described as “incompetent” or “insufficient” valves. Incompetent valves fail to keep the blood flowing through your heart in one direction. Blood leaking back through an incompetent valve, is commonly referred to as regurgitation. This valve problem may include a condition in which the valve flaps or “leaflets” flow backward with the leaking blood. This is called “valve prolapse.”

In the presence of regurgitation or stenosis the heart is required to work much harder. This extra work may cause your heart muscle to grow to accommodate the demands placed on it. An overworked, enlarged heart may begin to fail over time. Valve repair or replacement surgery can return a heart muscle to its original workload and size.

Despite attentive medical care, diseased heart valves may require surgical

attention. The aortic and mitral valves are the valves which most often need repair or replacement due to valve disease. In some cases the person's own valve can be surgically repaired to allow it to function in a normal way. Other people will require the valve to be replaced.

VALVE REPLACEMENT

During heart valve replacement surgery, one or more defective heart valves may be replaced. In this operation, your diseased valve will be removed and a substitute valve will be implanted. Substitute heart valves are called "prosthetic" valves. Two kinds of prosthetic valves are available: tissue (also called biologic or bioprosthetic) valves, and mechanical valves. Tissue valves more closely resemble the natural valves they replace and are well tolerated by the body without special medications. They are less durable than mechanical valves and may require replacement during a patient's lifetime. Mechanical valves are made of hard, durable materials that have been proven to be safe for use in the human body. Although mechanical valves last longer than tissue valves, they require that patients take daily medication to prevent blood clots from forming around the valve. The ATS 3f® Aortic Bioprostheses is a tissue heart valve.

The ATS 3f® Heart Valve is made from equine pericardium, which is heart tissue harvested from a horse and processed for human use. The valve is assembled into a tubular shape, and one end is covered with a fabric ring. This fabric ring is used to sew or attach the valve to a person's heart tissues. The 3f® Heart Valve transforms from its tubular shape into the shape of the aortic valve when the heart pumps. It opens and closes with each heart beat. A tissue heart valve can return the heart to its normal function and size over time.

LIVING WITH A TISSUE HEART VALVE

After your heart valve replacement surgery, you will be encouraged to return to your normal daily routines, with advice from your health care team. Most people feel better after their operation because the symptoms of their heart valve disease have been relieved. Your doctor will prescribe a program of recovery that includes diet, exercise and medications. It is very important that you follow your doctor's instructions.

Because your tissue heart valve is not native to your body, care must be taken to prevent bacteria from entering the blood stream and causing infective or bacterial endocarditis in the tissues around the valve. The best way to avoid this rare complication is to inform your dentist and other health care providers about

your heart valve. Antibiotics can be prescribed for you before your procedure to prevent possible infections or problems.

Tissue heart valve recipients need to be careful to take all prescription medications issued to them. In particular, your physician may prescribe anticoagulant medications and/or aspirin after surgery, often for 6-12 weeks. Anticoagulants work by prolonging the time it takes your blood to clot. Tissue heart valve patients take anticoagulants after surgery to prevent clots from forming around the valve while your body heals. Your doctor will determine the best anticoagulant regimen for you and will monitor proper levels with blood tests. Under your physician's guidance, anticoagulants may then be discontinued gradually, unless continued anticoagulation is indicated. It is important that you take only the medications your physician prescribes and to check before taking any over-the-counter medication. Consult your health care team if you notice unusual bruising, bleeding or blood in your urine while taking anticoagulants.

PATIENT I.D. CARD

Before you leave the hospital, the staff will provide you with a temporary patient identification card. This will be replaced with a permanent card once you return home. You should keep this card with you to provide health care providers with information about your tissue heart valve. If you move, ATS Medical should be notified so records can be updated. All of the information provided to your doctor or ATS Medical will be kept private.

PERSONAL INFORMATION

ATS Medical

3905 Annapolis Lane, Suite 105

Minneapolis, MN 55447

Patient Information: 1-866-295-3255

Date of surgery _____

Hospital _____

Cardiac Surgeon _____

ATS 3f® Heart Valve

Model # _____

Serial # _____

ATS Medical, Inc.
3905 Annapolis Lane
Minneapolis, MN 55447 (USA)
(763) 553-7736
(866) 287-6331
www.atomedical.com