MITROFLOW AORTIC
PERICARDIAL HEART VALVE

Sterile components: Mitroflow Aortic Pericardial Heart Valve and holder Non-sterile components: Exterior of valve container, Mitroflow aortic obturators and handles.

Model 12
INSTRUCTIONS FOR USE
ENGLISH

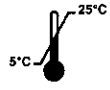
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

SYMBOL LEGEND


INSTRUCTIONS / WARNINGS: SEE MANUAL

CONTENTS STERILIZED USING ASEPTIC PROCESSING TECHNIQUE


USE BY



STORE BETWEEN 5°C AND 25°C


SINGLE USE ONLY


DO NOT RESTERILIZE

CATALOGUE NUMBER

SERIAL NUMBER

SIZE


MANUFACTURED BY

QUANTITY INCLUDED IN PACKAGE


DO NOT USE IF PACKAGE IS DAMAGED

These instructions contain important information on the use of the Mitroflow Aortic Pericardial Heart Valve and accessories. All personnel responsible for the storage, handling and implantation of the valve are advised to read and understand this information prior to use of the Mitroflow Aortic Pericardial Heart Valve (Mitroflow valve).

DEVICE DESCRIPTION

The Mitroflow valve consists of a single piece of bovine pericardium that is preserved with glutaraldehyde and sewn onto a polyester covered polymer stent. A radiopaque, silicone sewing ring is attached to the outer perimeter of the inflow side of the valve.

The valves are sterilized using glutaraldehyde/formaldehyde based liquid chemical sterilants, and are packaged in a sealed plastic jar containing sterile 4% formaldehyde storage solution.

The Mitroflow valve is available in aortic sizes 19, 21, 23, 25, and 27mm diameters.

INDICATIONS

The Mitroflow Aortic Pericardial Heart Valve is intended for the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.

CONTRAINDICATIONS

There are no known contraindications for the use of the Mitroflow valve.

WARNINGS AND PRECAUTIONS

- Clinical experience described in the medical literature suggests that juvenile patients or patients who are undergoing chronic hemodialysis, who have parathyroid disease or impaired calcium metabolism, or who are 55 years of age or less may experience accelerated calcification of bioprosthetic heart valves.
- **FOR SINGLE USE ONLY**
- Prior to opening the valve container, inspect the high and low temperature indicators on the valve carton for activation. Do not use the valve if either the high or low temperature indicators have been activated (See section **DIRECTIONS FOR USE**).
- All persons responsible for the handling and preparation of the valve for implantation must exercise utmost care to avoid damage to the valve, tissue, stent, and fabric.
- Do not pass any transvalvular diagnostic catheters or transarterial pacing leads through the in situ bioprosthesis. These procedures may cause damage to the valve.

Warnings Prior to Use

Do not use the Mitroflow valve:

- If the expiration date has elapsed
- If either the high or low temperature indicators in the valve carton have been activated
- If the valve container is damaged or has leaked
- If the tamper evident seal is broken
- If the bioprosthesis has been damaged
- If the storage solution does not completely cover the valve

Sterilization

- The Mitroflow valve cannot be resterilized. The valve container should never be subjected to sterilization procedures involving moist heat, ethylene oxide, chemical sterilants, or irradiation.
- The valve identification tag is not a sterility indicator.
- The Mitroflow reusable valve handles and aortic obturators must be cleaned and sterilized prior to use.

Precautions During Use

- The exterior of the valve container is non-sterile and should not be introduced into the sterile field.
- Once the tamper evident seal on the valve container is broken, the Mitroflow valve should be used immediately or contact your local sales representative to make arrangements for return or replacement.
- Do not allow the valve tissue to dry. Upon removal of the valve from the valve container, immediately place the valve in sterile physiological saline for rinsing.
- Adequate rinsing with sterile physiological saline is mandatory before implantation to reduce the formaldehyde concentration (see section **DIRECTIONS FOR USE**). No other solutions, drugs, chemicals, antibiotics, etc. should be added to the rinse solution as irreparable damage to the valve, which may not be apparent under visual inspection, may result.
- All persons responsible for the handling and preparation of the valve for implantation must exercise utmost care to avoid damage to the valve, tissue, stent, and fabric.
- Extreme care should be exercised when placing sutures through the sewing ring to avoid possible laceration of the tissue. **IF A VALVE IS DAMAGED, THE VALVE MUST BE EXPLANTED AND REPLACED.**
- Use only the Mitroflow obturators. Use of other obturators or other sizing techniques may result in misleading valve sizing information.

ADVERSE EVENTS

The clinical investigation of the Mitroflow Aortic Pericardial Heart Valve supports the safety of the Mitroflow valve. Table 1 presents the adverse event rates as observed in the clinical investigation.

Table 1. Observed Adverse Event Rates – Total Patients: N = 699, Cumulative follow-up 835.9 patient-years.

Adverse event	Early Events[1]		Late Events[2]		Percent Freedom From Event [SE][3]	
	n	% of Patients	n	%/Pt-Yr	1 Year	2 Years
All mortality	31	4.4	80	10.24	85.0 [1.4]	81.4 [1.8]
Valve-related death (includes sudden death)	2	0.3	18	2.30	96.7 [0.7]	96.7 [0.7]
Structural valve deterioration	0	0	2	0.26	99.8 [0.2]	99.4 [0.4]
All Anticoagulant-related bleeding	12	1.7	14	1.79	96.4 [0.7]	95.5 [1.0]
Major Anticoagulant-related bleeding	6	0.9	7	0.90	98.3 [0.5]	97.4 [0.8]
Thromboembolism	17	2.4	15	1.92	95.1 [0.9]	94.7 [0.9]
Major thromboembolic event	6	0.9	6	0.77	98.2 [0.6]	97.8 [0.7]
Valve Thrombosis	0	0	0	0	100 [0]	100 [0]
Endocarditis	1	0.1	19	2.43	96.8 [0.7]	96.4 [0.8]
Non-structural valve dysfunction[4]	4	0.6	6	0.77	98.6 [0.5]	98.2 [0.6]
Perivalvular Leak	4	0.6	4	0.51	98.7 [0.4]	98.7 [0.4]
Hemolysis	0	0	0	0	100 [0]	100 [0]
Reoperation (including explant)	0	0	9	1.15	98.5 [0.5]	98.5 [0.5]
Explant	0	0	8	1.02	98.7 [0.5]	98.7 [0.5]

[1] Early death occurred within 30 days of implant, and includes intraoperative deaths. Early valve-related events include postoperative events occurring 1-30 days post implant. Early event rates calculated as the percentage of patients with an event.
[2] Late postoperative events (>30 days post implant). Late event rates calculated as linearized hazard rates (%/patient-year). Calculations for linearized rates were based on 781.1 late patient-years.
[3] Freedom from first event (early or late) rates were calculated using the Kaplan-Meier method. SE = Standard error.
[4] Includes perivalvular leaks (8), and residual aortic stenosis (1) or insufficiency (1).

Potential Adverse Events

Adverse events potentially associated with the use of bioprosthetic heart valves (in alphabetical order) include (but may not be limited to):

- Angina
- Cardiac arrhythmias
- Endocarditis
- Heart failure
- Hemolysis
- Hemolytic anemia
- Hemorrhage
- Leak, transvalvular or perivalvular
- Myocardial infarction
- Non-structural dysfunction
  - Inappropriate sizing
  - Leaflet entrapment by tissue in-growth
  - Prosthesis regurgitation
  - Prosthesis stenosis
  - Suture entrapment on commissures
- Stroke
- Structural valve deterioration
  - Intrinsic and extrinsic mineralization (calcification)
  - Leaflet perforation or tear
  - Leaflet rupture
- Thromboembolism
- Valve thrombosis

It is possible that these complications could lead to:

- Reoperation
- Explant
- Permanent disability
- Death

While these complications have not been observed in the majority of patients after cardiac valve replacement, the surgeon should carefully weigh the potential of such an adverse event in selecting the optimum valve replacement for each patient.

CLINICAL STUDY

A prospective, non-randomized, multicenter clinical study was conducted on 699 patients requiring isolated aortic valve replacement (AVR) with the Mitroflow Aortic Pericardial Heart valve. Cumulative follow-up of the study cohort was 835.9 patient-years, with mean follow-up of 14.4 months. The patients underwent AVR between November 2003 and December 31, 2005 at 25 centers (28 hospitals) in the United States (20 centers) and Canada (5 centers).

In the study population, there were 397 (56.8 %) males and 302 (43.2%) females with a mean age at implant of 74.3 years and an age range of 27 to 93 years. The primary indications for valve replacement were calcification 93.6%, congenital anomalies 13.7%, rheumatic heart disease 4.1%, and previous valve implant 1.4%. Follow-up methods used included hospital visits or clinic visits.

Table 2 presents by valve size, the mean gradients, effective orifice area, and valve regurgitation as reported in echocardiograms performed on patients in the study population.

Table 2. Effectiveness Outcomes, Hemodynamic Results[1] at 1 Year: Isolated AVR (N = 544).

Hemodynamic Data	Valve Size[2]				
	19 (N[3] =34)	21 (N=143)	23 (N=193)	25 (N=128)	27 (N=42)
Mean gradient (mmHg)	n[4] =33	n=136	n=189	n=122	n=39
Mean ± SD	13.4 ± 5.0	11.4 ± 4.4	10.5 ± 4.2	8.7 ± 3.3	7.4 ± 2.7
Effective orifice area (cm^2)	n=30	n=131	n=185	n=121	n=37
Mean ± SD	1.1 ± 0.2	1.2 ± 0.3	1.4 ± 0.3	1.6 ± 0.3	1.8 ± 0.3
Regurgitation	n=34	n=143	n=193	n=128	n=42
None	21 (61.8%)	103 (72.0%)	145 (75.1%)	98 (76.6%)	33 (78.6%)
Trace	8 (23.5%)	18 (12.6%)	35 (18.1%)	22 (17.2%)	4 (9.5%)
Mild	4 (11.8%)	20 (14.0%)	13 (6.7%)	6 (4.7%)	5 (11.9%)
Moderate	1 (2.9%)	1 (0.7%)	0 (0.0%)	2 (1.6%)	0 (0.0%)
Severe	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Not Reported	0 (0.0%)	1 (0.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

[1] Hemodynamic evaluation performed using transthoracic echocardiography.
[2] Size 29mm 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.
[3] N = total patients with echo evaluation in each valve size.
[4] n = patients in each valve size with valid measurement of hemodynamic parameter.

Information on preoperative and postoperative NYHA Functional Classification was gathered on all study patients. At their 3-6 month follow up 97.6% of patients were in NYHA Class I/II compared to 47.2% in preoperative NYHA Class I/II (Table 3). At 12 months 98.6% of the patients were in NYHA Class I/II. At 2 years 97.6% were in Class I/II.

Table 3. NYHA Functional Classifications.

NYHA Class	Preoperative (N=692)[1]		Postoperative Assessments					
			3-6 months (N=571)		1 year (N=544)		2 years (N=245)	
	n[2]	%	n	%	n	%	n	%
I	62	9.0	431	75.1	427	78.5	188	76.7
II	264	38.2	129	22.5	109	20.0	51	20.8
III	300	43.4	11	1.9	6	1.1	6	2.4
IV	66	9.5	3	0.5	2	0.4	0	0.0

[1] N = total number of patients with NYHA evaluation at each postoperative assessment.
[2] n = number of patients in each NYHA category.

INDIVIDUALIZATION OF TREATMENT

Anticoagulant and/or Antiplatelet Therapy

Extensive published data indicates that some form of anticoagulant and/or antiplatelet therapy may be beneficial after cardiac valve replacement with a bioprosthesis to reduce the risk of valve thrombosis and/or thromboembolic phenomenon.

In general, for bioprostheses, anticoagulation therapy is recommended for 90 days after aortic valve replacement.

Indefinite therapy with low dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Indefinite anticoagulation therapy, unless contraindicated, is recommended for patients with the thromboembolism risk factors of moderate to severe atrial wall calcification or other atrial wall abnormalities, atrial fibrillation, left ventricular dysfunction, a hypercoagulable condition, or a prior history of thromboembolic events, consideration should be given to prescribing indefinite anticoagulation therapy.

Specific Patient Populations

Clinical experience described in the medical literature suggests that juvenile patients or patients who are undergoing chronic hemodialysis, who have parathyroid disease or impaired calcium metabolism, or who are 55 years of age or less may experience accelerated calcification of bioprosthetic heart valves. Risks and benefits of using glutaraldehyde-preserved bioprosthesis in these patients should be carefully weighed by the physician when selecting the appropriate valve replacement for patients with one or more of the above factors.

The medical literature indicates that children who undergo heart valve replacement may require subsequent valve replacement procedures as a result of normal cardiac tissue development.

PATIENT COUNSELING

Patients undergoing any dental procedures which are potentially bacteremic should receive prophylactic antibiotic therapy.

Indefinite therapy with low dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Indefinite anticoagulation therapy, unless contraindicated, is recommended for patients with the thromboembolism risk factors of moderate to severe atrial wall calcification or other atrial wall abnormalities, atrial fibrillation, left ventricular dysfunction, a hypercoagulable condition, or a prior history of thromboembolic event or events.

Patients should use the identification card that contains patient and valve information for future reference.

DIRECTIONS FOR USE

The Mitroflow valve is supplied sterile and non-pyrogenic in a 4% formaldehyde solution in a sealed container.

The valve shall not be used if:

1) The expiration date has elapsed
2) Either the high or low temperature indicators in the valve carton have been activated
3) The valve container is damaged or has leaked
4) The tamper evident seal is broken
5) The bioprosthesis has been damaged
6) The storage solution does not completely cover the valve.

For information regarding the return of any product, contact your local sales representative. A required "Return Goods Authorization" number and packaging instructions shall be provided. Explanted valves should be placed into a suitable histological fixative such as 10% formalin before being returned.

Pre-Operative Handling

It is recommended that the special obturators designed for use with the Mitroflow valve be used for valve size selection. The Mitroflow obturators will aid in choosing the appropriate size of valve to be used in the patient. **OBTURATORS AND HANDLES FROM OTHER MANUFACTURERS ARE NOT SUITABLE FOR USE WITH THE MITROFLOW VALVE AND SHOULD NOT BE USED.** The Mitroflow handles and obturators are supplied NON-STERILE and must be cleaned and sterilized prior to each use. Do not use obturators if there are signs of damage or aging such as cracking or crazing. Do not use obturators if printed text is not legible or the obturator appears to be damaged. Contact your sales representative for instrument replacement.

All instrumentation must be wrapped for sterilization. Obturators must not be exposed to temperatures above 137°C (279°F). It is recommended that the handles and obturators be sterilized by steam (autoclaving). Refer to section **ACCESSORY CLEANING AND STERILIZATION**.

Refer to the instrumentation instructions for use provided with the obturators and handles for further information.

The Mitroflow obturators are designed to assist the surgeon in accurately sizing the aortic valvular annulus for use with an appropriately sized Mitroflow valve in either supra-annular (Fig. 1) or intra-annular (Fig. 2) placement.

The largest obturator dimension reflects the dimension of the valve sewing cuff in the relaxed position.

The Mitroflow handle is used with the obturators for sizing, and with the Mitroflow valve holder for implantation.

To attach the handle (Fig. 3), thread the handle into the obturator or valve holder with a clockwise rotation. The valve handle is separated by a counter clockwise rotation.

Select a valve that will snugly fit into the aortic annulus for intra-annular placement or fit into the aortic root (Sinus of Valsalva) for supra-annular placement. Care should be taken to prevent insertion of the obturator into the valvular annulus at an angle or to prevent selecting an obturator size that does not provide sufficient contact with the valvular annulus.

Mitroflow valves should not be oversized. Mitroflow valves are for **SINGLE USE ONLY**. Selection of the proper size valve is the responsibility of the implanting surgeon.

Each Mitroflow valve has a disposable valve holder attached at the time of manufacture. In addition, this holder is positioned by a packaging insert to aid in removal of the valve from the container and storage solution.

Device Preparation Prior to Implant

1. After selecting the appropriate size valve, obtain the correct valve size carton.
2. Before removing the valve container, inspect the low and high temperature indicators. Do not use the valve if either the high or low temperature indicators have been activated (see section **HOW SUPPLIED**).
3. Remove the valve container from the carton. Verify that all carton and container labels match with respect to valve model, size, and serial number. **IN THE EVENT OF ANY NON-MATCHING INFORMATION, DO NOT USE THE VALVE**. Contact your local sales representative to make arrangements for return or replacement.
4. Carefully inspect the entire valve container and tamper-evident seal for damage. **DO NOT USE THE VALVE IF THE VALVE CONTAINER IS DAMAGED OR IF THE SEAL IS BROKEN.**
5. Before opening the valve container, prepare **THREE TALL** rinse basins, each containing 300 ml of sterile physiologic saline.
6. Remove the tamper-evident seal and shrink-wrap from the valve container and unscrew the container lid. The contents of the jar are sterile and must be handled aseptically to prevent contamination. The outside of the jar is not sterile and must not enter the sterile field.
7. To remove the valve from the container, insert the threaded area of the Mitroflow handle into the valve holder orifice. Thread the handle clockwise into the top of the valve holder until tight (Fig. 4).
8. Hold onto the jar and lift the packaging insert and valve out of the valve container (Fig. 5) and into the sterile field.

BOTH THE VALVE AND 4% FORMALDEHYDE PACKAGING SOLUTION ARE STERILE. THE EXTERIOR OF THE CONTAINER IS NON-STERILE AND MUST NOT BE INTRODUCED INTO THE STERILE FIELD.

ANY VALVE THAT IS DROPPED, DAMAGED, OR MISHANDLED IN ANYWAY SHOULD NOT BE USED FOR IMPLANTATION.

CONTACTING THE VALVE WITH COTTON SWABS MAY LEAVE COTTON FIBERS ADHERING TO THE PERICARDIAL LEAFLETS THAT COULD EMBOLIZE OR SERVE AS A NIDUS FOR THROMBUS DEVELOPMENT.

METICULOUS CARE SHOULD BE GIVEN TO PREVENT CONTAMINATION OF THE VALVE STORAGE SOLUTION BY GLOVE POWDER.

9. Grasp the packaging insert and slide the thin part of the holder through the slot in the packaging insert (Fig. 6). Discard the packaging insert.
10. Submerge the valve in the first rinse basin of sterile saline solution. It is recommended that a tall rinse basin be used to prevent the handle from tipping over causing the valve to fall out of the basin.
11. Verify that the information on the identification tag attached to the valve matches the corresponding information on the container, carton, and Patient Registration Form. Do not implant the valve if the data are not identical.
12. Detach the identification tag by cutting the suture attachment with scissors and removing all tag suture material (Fig. 7).
13. By grasping the handle, gently agitate the valve for two minutes in the first rinse basin. Repeat the two-minute rinse in the second and third basins for a total rinse time of at least six minutes. DO NOT TOUCH THE LEAFLETS OR SQUEEZE THE VALVE DURING RINSING.
14. Allow the valve to remain in the third basin until required by the surgeon. DO NOT ALLOW THE TISSUE TO DRY DURING THE HANDLING AND IMPLANTATION OF THE VALVE AS THIS COULD RENDER THE VALVE UNFIT FOR USE.

Device Implantation

Prior to suturing the valve into the annulus, identify the direction of flow through the valve to ensure proper orientation and subsequent function.

Orient the valve so that the coronary ostia are not compromised.

Do not handle the tissue portion of the valve with instruments.

During implantation, frequently irrigate the valve tissue with sterile, physiologic saline to prevent dehydration.

Operating Room (OR) personnel should hold the valve handle during the entire suturing of the sewing cuff.

Do not use cutting edge suture needles, as these will damage the valve sewing ring.

If interrupted sutures are used, care must be exercised to cut the sutures close to the knots and to ensure that suture tails do not come into contact with leaflet tissue.

Extreme care should be exercised when placing sutures through the sewing ring to avoid possible laceration of the tissue. IF A VALVE IS DAMAGED, THE VALVE MUST BE EXPLANTED AND REPLACED. DO NOT ATTEMPT TO REPAIR DAMAGE TO THE VALVE THAT MAY OCCUR DURING INSERTION.

Looping or catching a suture around the commissural posts will interfere with valve clinical performance.

Diligent attention is required by the surgeon while suturing the sewing ring to the annulus to avoid the occurrence of perivalvular leaks.

Following placement of the valve in the patient annulus, remove the handle-holder as a unit by severing the three exposed holder retaining sutures on the right hand side of the knots (Fig. 8). Use a uniform motion to pull the handle away from the implanted valve. Verify that all remaining suture material has been removed from the sewing cuff.

After detaching the handle-holder unit, the holder and retaining sutures should be removed and discarded.

The valve storage solution contains formaldehyde and may cause irritation of skin, eyes, nose, and throat. Do not breathe storage solution vapor. Avoid prolonged skin contact with the formaldehyde solution, and if such contact occurs, immediately flush area with copious amounts of water. In case of contact with eyes, seek medical assistance immediately.

It is beyond the scope of these instructions for use to instruct the surgeon in specific valve replacement surgical procedures. Reference should be made to pertinent scientific literature.

PATIENT INFORMATION

It is the responsibility of the implanting surgeon to inform the patient of the following symptoms that indicate improper functioning of the replacement heart valve.

A Mitroflow valve recipient should seek medical attention if they experience any of the following: angina, syncope, shortness of breath during exertion, orthopnea, paroxysmal nocturnal dyspnea, palpitations, ankle swelling, general weight gain, shaking chills, fevers, night sweats, visual disturbance, unexpected petechiae, splinter hemorrhage,

flame hemorrhage, painful joints, painful spots in the toes, fingers, or soles of the feet, hemoptysis, hematuria or gastrointestinal disturbance.

Magnetic Resonance Imaging (MRI)

Non-clinical testing has demonstrated that the Mitroflow valve is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3.0 Tesla or less
- Spatial gradient field of 525 Gauss/cm or less
- Maximum whole-body-averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of scanning.

In non-clinical testing, the Mitroflow valve produced a temperature rise of less than 0.8°C at a maximum whole body averaged specific absorption rate (SAR) of 1.5 W/kg for 20 minutes of MR scanning in a 1.5 Tesla, Model Signa MR, GE Medical System, Milwaukee, WI, MR scanner.

MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Mitroflow valve. Therefore, it may be necessary to optimize MR imaging parameters to compensate for the presence of this implant.

Patient Registration Form

A Patient Registration Form is enclosed in each valve carton. The registration form must be completed and returned as directed on the Patient Registration Form. Upon receipt of the form, an identification card will be prepared with patient and valve information and sent to the patient.

HOW SUPPLIED

The Mitroflow valve is supplied sterile and non-pyrogenic in a sealed container, preserved in a 4% formaldehyde storage solution. Each valve is packaged individually in its own container. The valve packaging system is designed to facilitate convenient aseptic transfer of the valve to the sterile field.

After implantation of the Mitroflow valve, the 4% formaldehyde storage solution should be disposed according to hospital procedure.

Temperature Indicators to Indicate Shipping Conditions

Each shipping carton contains high and low temperature indicators (Fig. 9) to indicate whether extreme hot and/or cold temperatures have been encountered during shipping.

The low temperature indicator contains a white background that will become dark-stained (Fig. 10) if the valve has been exposed to excessive cold temperatures.

The high temperature indicator will turn BLACK (Fig. 10) if the product has been exposed to excessive heat.

If either the high or low temperature indicator has been activated (Fig. 10), DO NOT USE THE VALVE. Immediately contact your local sales representative to make arrangements for return and replacement.

STORAGE CONDITIONS

The Mitroflow valve must be stored at a temperature between +5°C and +25°C (41°F - 77°F). Avoid locations where extreme temperature fluctuations may occur; e.g. near steam, hot water pipes, air conditioning ducts, direct sunlight, etc. REFRIGERATION IS NOT REQUIRED. Although refrigeration at 5°C (41°F) is acceptable, the risk of undetected freezing must be considered. FREEZING MAY SERIOUSLY DAMAGE THE VALVE AND RENDER IT UNFIT FOR USE. DO NOT STORE UNDER REFRIGERATION UNLESS CONTINUOUS TEMPERATURE MONITORING IS MAINTAINED. Storage life of the bioprosthesis is 60 months from the date of sterilization.

ACCESSORY CLEANING AND STERILIZATION

The Mitroflow handles and obturators are supplied NON-STERILE and must be cleaned and sterilized prior to each use. Do not use obturators if there are signs of damage or aging such as cracking or crazing. Do not use obturators if printed text is not legible or the obturator appears to be damaged. Contact your sales representative for instrument replacement.

Cleaning and Disinfection Instructions for Mitroflow Instrumentation

MITROFLOW INSTRUMENTS MAY BE DAMAGED BY STRONGLY ALKALINE OR STRONGLY ACIDIC DETERGENTS AND SOLUTIONS, AND BY CHEMICALS CONTAINING KETONES OR CHLORINATED SOLVENTS.

It is recommended that instruments be reprocessed as soon as reasonably practical following use. The following cleaning and disinfection methods are recommended for Mitroflow instrumentation:

Manual Cleaning and Disinfection

1. Wipe instrument with wet, disposable sponge to remove gross soil.
2. Rinse instrument in hot, running tap water for a minimum of 20 seconds to remove visible soil.
3. Soak instruments in a bath of either (a) Wescodyne for five minutes, or (b) Terg-A-Zyme Enzymatic Cleaner (Alconox).
4. Scrub instrument thoroughly with a soft bristle brush.
5. Rinse instrument with de-ionized water for a minimum of 20 seconds to remove remaining soil and cleaning agent.

Washer-Disinfector with Alkaline Detergent+

After placing the instruments in the washer-disinfector, perform the following programmed cleaning cycles:

Step	Cycle	Duration	De-ionized Water	Comments
1	Pre-Wash	2 minutes	45 °C ± 5 °C	Do not use detergents or additives. Drain when complete.
2	Pre-Wash	2 minutes	45 °C ± 5 °C	Do not use detergents or additives. Drain when complete.
3	Wash	10 minutes	45 °C ± 5 °C	Follow instructions from manufacturer of washer-disinfector for optimal mix ratio and concentration of alkaline detergent. Drain when complete.
4	Rinse	1 minute	45 °C ± 5 °C	Do not use neutralizers in the rinse. Drain when complete.
5	Rinse	2 minutes	91 °C ± 5 °C	Do not use neutralizers in the rinse. Drain when complete.
6	Dry	10 minutes	----------	Forced Air at 91 °C

+ Testing was conducted using HAMO T-21 washer-disinfector with HAMO Liquid 55 alkaline detergent (Deconex 22 LIQ equivalent) utilizing mix ratio of 4 ml of detergent per liter of water in the wash.

Washer-Disinfector with Enzyme Detergent*

After placing the instruments in the washer-disinfector, perform the following programmed cleaning cycles:

Step	Cycle	Duration	Tap Water	Comments
1	Pre-Wash	5 minutes	50 °C ± 5 °C	Do not use detergents or additives. Drain when complete.
2	Pre-Wash	5 minutes	50 °C ± 5 °C	Do not use detergents or additives. Drain when complete.
3	Wash	10 minutes	60 °C ± 5 °C	Follow instructions from manufacturer of washer-disinfector for optimal mix ratio and concentration of enzyme detergent. Drain when complete.
4	Rinse	5 minutes	90 °C ± 5 °C	Drain when complete.
5	Rinse	5 minutes	90 °C ± 5 °C	Drain when complete.
6	Cool	5 minutes	----------	Remove parts from washer-disinfector and cool at room temperature.

* Testing was conducted using Getinge/Castle washer- disinfector with Castle® Renuzyme enzyme detergent.

Based on testing, it was determined that reusable instrumentation could be cleaned and disinfected a total of 100 cycles using the above washer-disinfector based cleaning and disinfection methods. Note that changes to these cleaning and disinfection methods may result in reduced instrument life cycles.

Sterilization Instructions for Mitroflow Instrumentation

All Mitroflow instrumentation must be cleaned and steam sterilized prior to initial use and each reuse. A maximum of two (2) handles and five (5) obturators may be sterilized in the Mitroflow Aortic Pericardial Heart Valve Accessory Tray; the accessory tray should not be used if it is damaged.

Mitroflow instrumentation shall be wrapped and steam sterilized according to the following minimum parameters:

Sterilization Instructions for Mitroflow Instrumentation				
Container	**Wrapped Instruments**	**Wrapped Tray**	**Wrapped Tray**	**Wrapped Instruments**
Temperature	121 °C (250 °F)	121 °C (250 °F)	132 °C (270 °F)	134 °C (273 °F)
Time	35 minutes	35 minutes	10 minutes	3 minutes
Cycle	Pre-Vacuum	Pre-Vacuum	Pre-Vacuum	Pre-Vacuum

Follow instructions provided by the manufacturer of the sterilization equipment and established hospital procedures. It is the responsibility of each institution to validate the process and to establish the efficacy of their procedure.

VALVE SPECIFICATIONS

Mitroflow Aortic Pericardial Heart Valve – Model 12

	A*	B*	C*	D*	
Model	Inside Diameter (mm)	Outside Diameter (mm)	Overall Height (mm)	Sewing Ring Width (Relaxed) (mm)	** Effective Orifice Area (cm^2)
12A19	15.4	18.5	11	21	1.6
12A21	17.3	20.6	13	24	2.0
12A23	19.0	22.6	14	26	2.4
12A25	21.0	25.0	15	28	3.0
12A27	22.9	27.2	16	32	3.5

*Dimensions illustrated in Fig. 11 below

** In vitro data on file

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PRODUCT AVAILABILITY

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Distributed in U.S.A. by:

CarboMedics Inc.
14401 West 65th Way
Arvada, Colorado 80004 U.S.A
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FIGURES

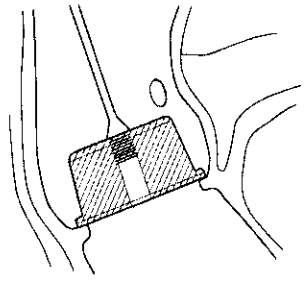


Fig. 1

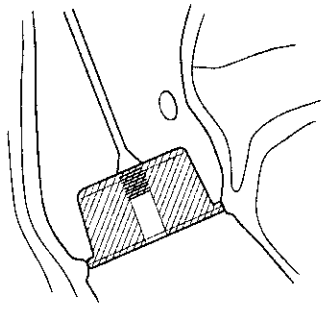
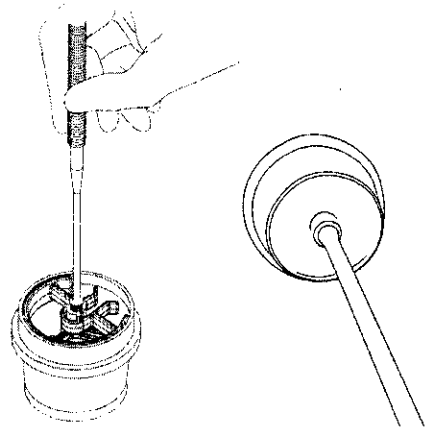


Fig. 2



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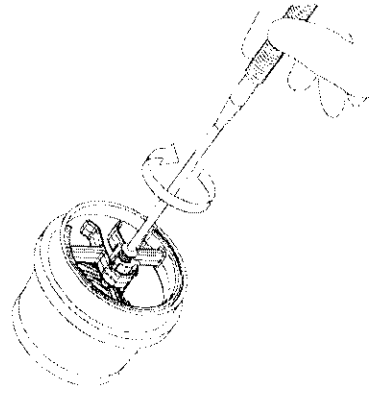

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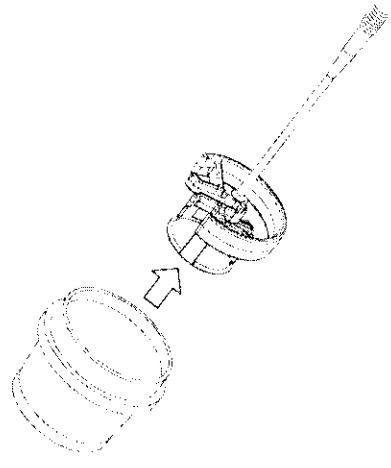

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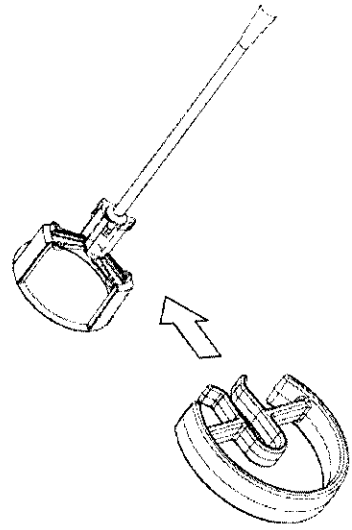

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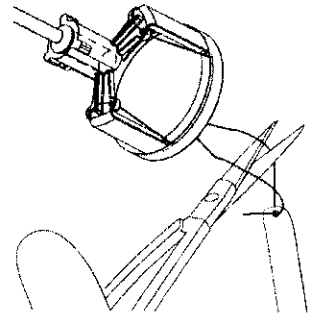

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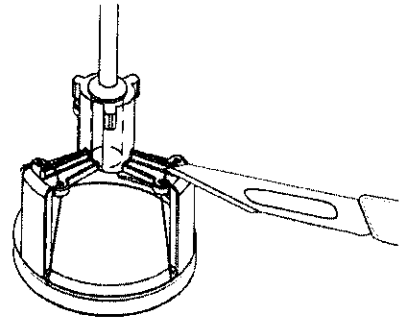


Fig. 8

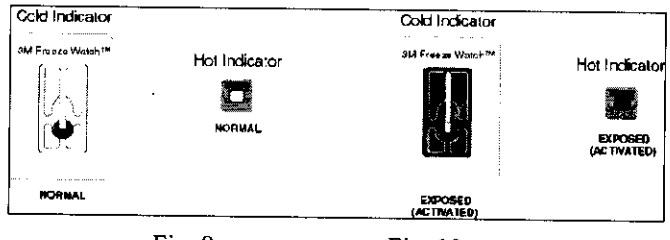


Fig. 9 Fig. 10

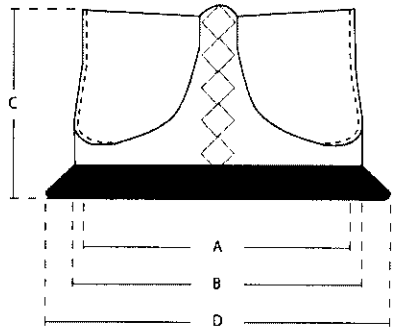
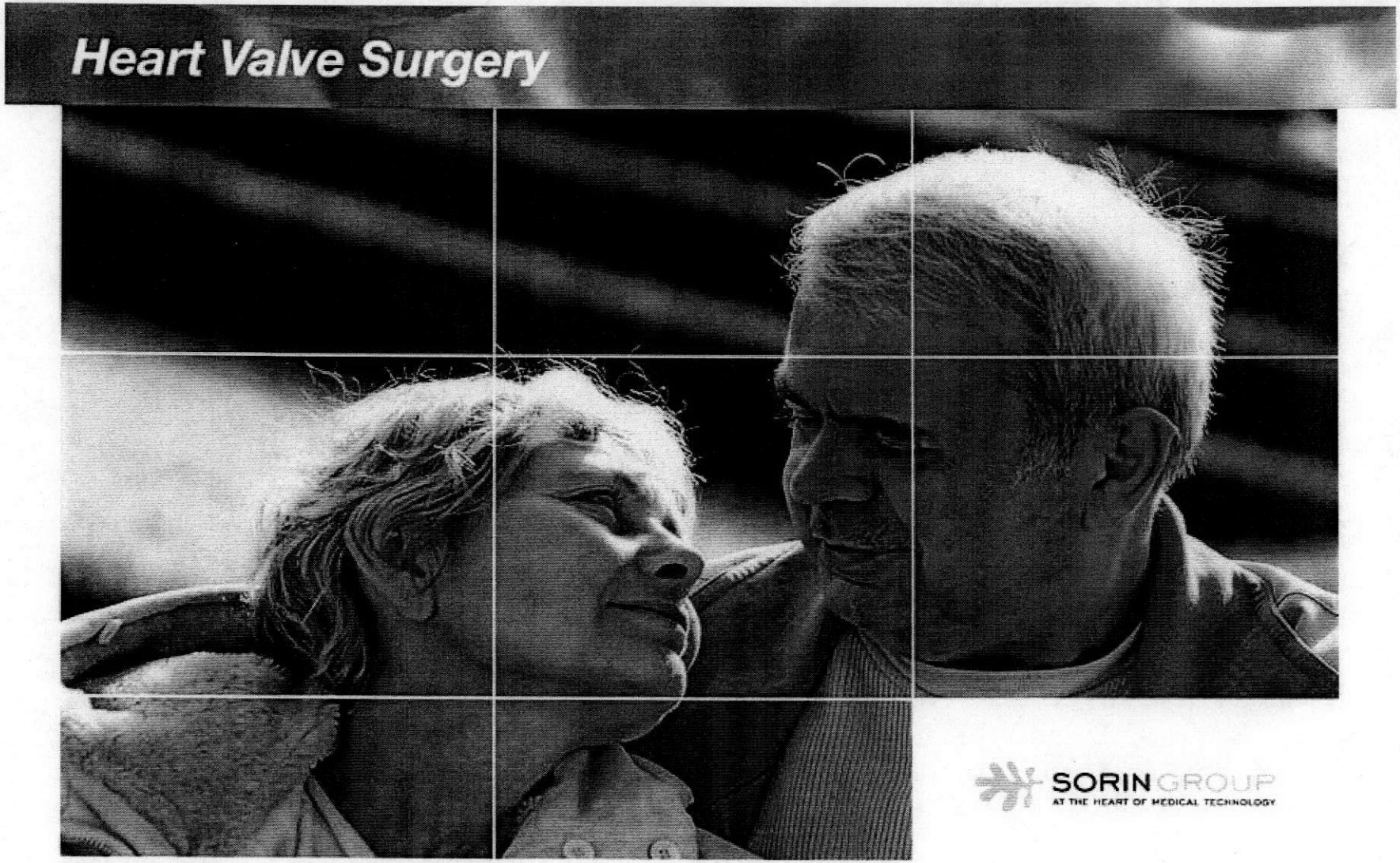


Fig. 11


Heart Valve Surgery
SORIN GROUP
AT THE HEART OF MEDICAL TECHNOLOGY

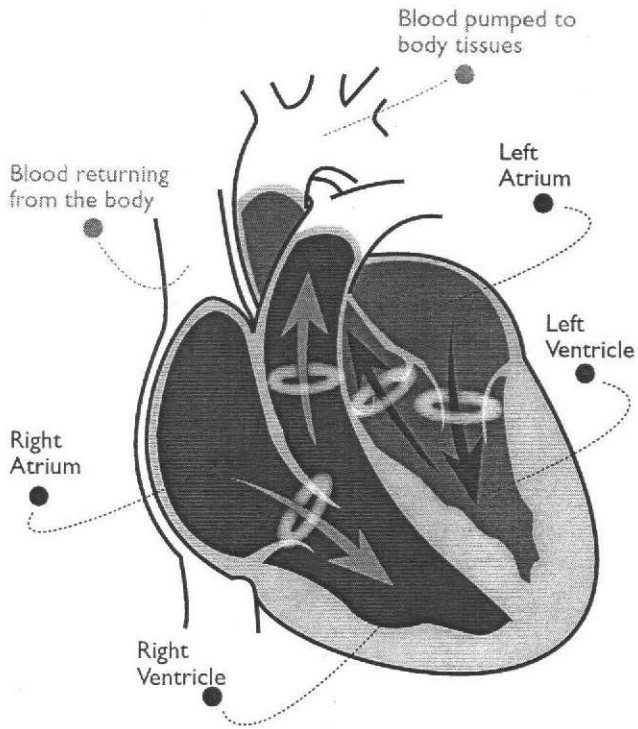
This booklet is provided for your information by Sorin Group, a leading provider of prosthetic heart valves and cardiac repair products through Carbomedics Inc. and Sorin Group Canada Inc., Mitroflow Division.

The topics included will help you understand and prepare for heart valve surgery.

It gives a basic explanation of heart valve anatomy, the usual course of events, and the expected recovery. It will answer many commonly asked questions.

This booklet is not intended to replace the instructions, care, and advice of your physician. If you have further questions, write them down in the space provided in the back of this booklet to discuss with your physician.

Contents



Your Heart

The healthy heart weighs well under a pound and is only a little larger than your fist. It is a powerful, continuously hard-working organ. In addition to maintaining a steady, normal flow of blood it must be able to adjust and adapt quickly to the body's ever changing needs. For example, it must pump more blood with strenuous activity and less blood when you are at rest. In an average day, the heart will contract an average of 60 to 90 times per minute - 42 million heartbeats per year!

Your heart is actually a two-sided pump responsible for circulating blood throughout your body. Inside your heart there are four chambers. A wall of muscle called the septum divides your heart into a left side and a right side.

Each side has two chambers. The upper chambers are called atria and the lower chambers are the ventricles. The right atrium receives all the returning blood from the upper and lower part of the body. It then transfers this blood through the tricuspid valve to the right ventricle, which then pumps the blood through the pulmonary valve out to the lungs. In the lungs, carbon dioxide is exchanged for oxygen then the blood returns to the left atrium, which transfers it through the mitral valve into the left ventricle. The left ventricle then pumps the blood through the aortic valve and throughout the body via the arteries where the blood supplies tissues with oxygen and removes carbon dioxide. The blood, now depleted of oxygen, is returned to the right atrium by the veins.

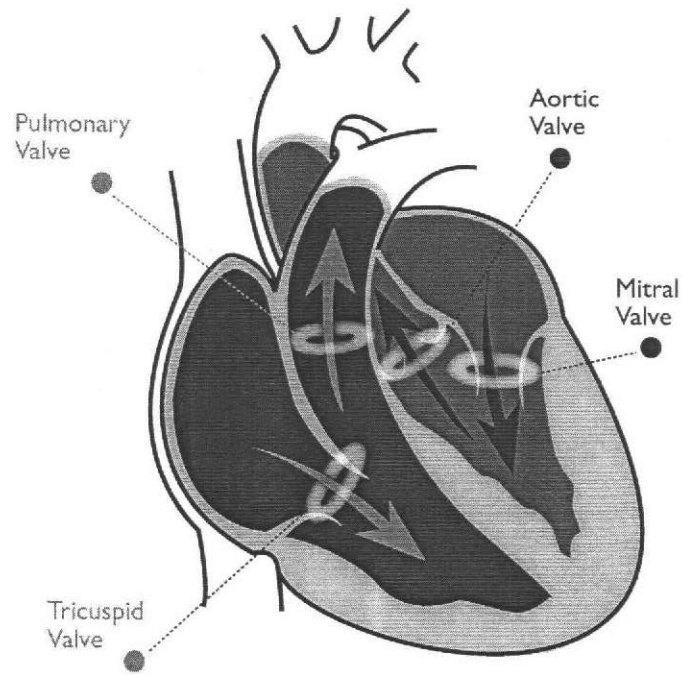
Heart Valves

Let's look at what heart valves do as well as how and why natural heart valves fail and how it affects the heart and circulatory system.

The four valves (tricuspid, pulmonary, mitral, aortic) act as one-way doors between the chambers. These valves allow forward flow and prevent backflow of blood moving through the heart. Healthy valve leaflets are perfectly formed thin, pliable tissues that open and close as your heart contracts and relaxes.

Heart valves can be abnormally formed as birth defects. They can be damaged or scarred by rheumatic fever, infection, or inherited conditions. The aortic and mitral valves are the ones most often affected. Regardless of the cause, the heart valve may become stenotic (narrowing of the valve opening) or incompetent (does not close completely). Valve stenosis requires the heart to work harder to pump the blood past the narrow opening. The incompetent valve will allow blood to leak backwards through the valve once it has closed. In either case, the heart must work harder to pump enough blood for the body's needs.

This excess work can weaken the heart causing it to enlarge and produce various symptoms. Some of these symptoms are chest pain, shortness of breath, dizziness, fainting, chronic tiredness, and swelling of the feet and legs.



Treatment of Valve Disease

With careful medical supervision, many people with heart disease live reasonably normal lives using medication. However, when medical treatment is not indicated or is dangerous or ineffective, your physician may recommend a surgical procedure to repair or replace the damaged valve or valves.

In some cases it is possible to repair a valve by performing a surgical procedure called valvotomy, valvuloplasty, or valve repair. Some valves are so seriously deformed or diseased that they must be removed and replaced with a prosthetic (artificial) heart valve.

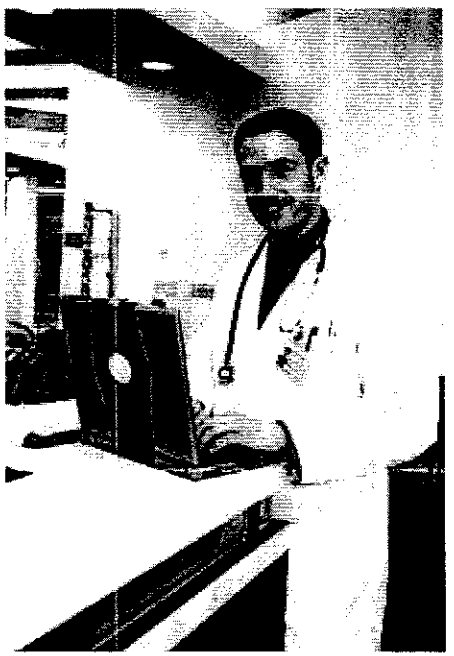
Today, there are several replacement valve options available within two broad categories of valve types, mechanical heart valves and bioprosthetic or tissue heart valves.

Mechanical heart valves are constructed with strong, man-made materials. The most important benefit of mechanical valves is that they are the most durable, able to last the lifetime of the patient. Patients with mechanical replacement heart valves must take daily blood anticoagulation medication to minimize the risk of complications from blood clots.

Bioprosthetic heart valves are made with tissue from porcine (pig) heart valves or bovine (cow) cardiac tissue. These tissue replacement heart valves are designed to function like natural heart valves.

The most important benefit of this type of valve is that the valve is very compatible with the blood stream. Patients with tissue valves are not always dependent on daily medication to minimize complications from blood clots.

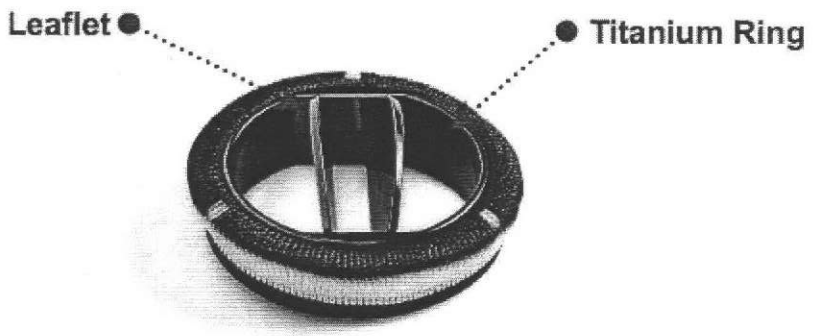
Your physician can help you make the decision between a mechanical heart valve and a bioprosthetic (tissue) heart valve. The decision may be based on your age, lifestyle, medication requirements, and other factors.



Carbomedics Prosthetic Heart Valve

The Carbomedics Prosthetic Heart Valve is a low profile mechanical valve consisting of an orifice and two leaflets that open and close to control the flow of blood.

The Carbomedics Prosthetic Heart Valve is made of materials with a long and satisfactory history of use in cardiovascular applications. The leaflets and orifice utilize Pyrolite® carbon, a material used extensively in mechanical heart valves. The carbon valve orifice is reinforced by a titanium ring that minimizes the potential for orifice deformation. The housing and reinforcing ring are surrounded by a polyester fabric sewing ring. The blood contact surfaces of the sewing ring on some models are coated with carbon.



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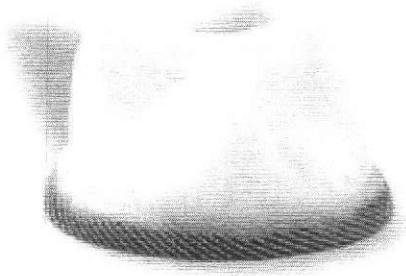
Mitroflow Aortic Pericardial Heart Valve

The Mitroflow® Aortic Pericardial Heart Valve is a bovine pericardial valve designed as a replacement for malfunctioning native aortic valves due to acquired or congenital heart disease, or as a replacement for a malfunctioning previously implanted prosthetic valve.

The Mitroflow Aortic Pericardial Heart Valve was designed to overcome the limitations seen in earlier model tissue heart valves, specifically to increase the opening area of the valve making it easier for the heart for pump blood through the valve. The valve consists of a single piece of bovine pericardium treated with glutaraldehyde and sewn onto a plastic frame covered with polyester fabric. A silicone sewing ring is attached to the side of the valve. The pericardial tissue thickness is matched to the valve size to ensure proper operation of the leaflets.

The Mitroflow Aortic Pericardial Heart Valve has been in worldwide clinical use since 1982.



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Before Surgery

If you have some time to wait before your surgery, your physician and surgeon can advise you on ways to prepare yourself, including medication and exercise. One of the most important considerations before any surgery is preparation of the lungs. If you smoke, you should stop smoking as early as possible before your surgery. Smoking constricts the coronary arteries, promotes blood clotting, produces excess mucous in the lungs, raises the blood pressure, and makes the heart beat faster.

All of these conditions have the tendency to increase the potential for complications after surgery.

Surgery

Once you are in the operating room, several monitoring devices will be attached to your arms and legs. There will be thin tubes placed in a vein and an artery. This is ordinarily not painful. The anesthesiologist will administer the anesthetic which will bring deep sleep, freedom from pain and absence of memory of the operation. During surgery a heart-lung bypass machine will take over the normal functions of your heart and lungs allowing the surgeon to replace or repair your heart valve.

After Surgery

After surgery, the staff will take you to an intensive care unit or recovery room. While you are in this area you will be monitored constantly by a highly trained staff.

Anesthetics wear off at different rates. Some people respond in an hour or two, but most people take longer. You may be able to hear or open your eyes before you can move your arms and legs. Soon your mind and body will be fully responsive.

When you awaken, you may find you have a tube in your mouth that is preventing you from talking. This is a breathing tube connected to a respirator. The respirator will take care of your breathing until you have recovered enough to breathe on your own. Even though you may not be able to talk because of the tube in your mouth, the nurses that are caring for you are very experienced and will be able to understand your needs using various signs and written communication.

The breathing tube and other tubes and wires will be removed at various time periods after surgery. Drainage tubes running from your chest will prevent fluid from gathering around your heart. A urinary catheter in your bladder will allow the urine to be measured to determine kidney function. Intravenous tubes (I.V.) in your arms are to administer fluids and medications. Other lines that may be in the neck area or wrist directly monitor the function of the heart and blood pressure. Electrode patches and wires on the skin are used to monitor your heart rate and rhythm.

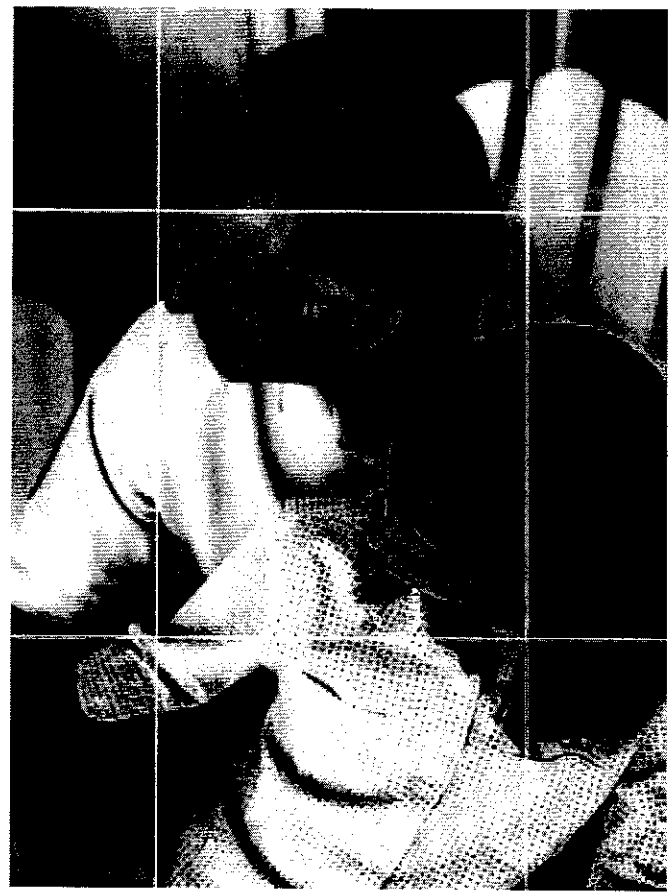
Once the breathing tube is removed, you will be encouraged to breathe deeply and cough to help eliminate secretions from your lungs. Your nurse or therapist can help you do this safely and as comfortably as possible.

Keeping your lungs clear is a precaution against pneumonia and is an important factor in your recovery.

In the intensive care unit you will be given medication at regular intervals. This and other factors may cause some disorientation and confusion. If this happens to you, do not be concerned since this is not unusual and will not last long. Most patients complain of being sore and stiff but usually do not have severe pain.

Risks

There are risks with any heart valve replacement. These may include, but are not limited to, blood cell damage (hemolysis), low red blood cell count (Hemolytic anemia), bleeding, infection, clotting in or on the valves (thrombus formation), tissue on the valve (valvular pannus), loose clots in the blood stream that may block an artery in your arms, legs or brain (thromboembolism), valve failure (which may include structural damage), leakage around the edge of the valve (paravalvular leak), need for reoperation, explantation, arrhythmia (irregular heart beat), stroke, angina, heart failure, and death.



Out of Intensive Care

When your physician determines that you no longer need to be in intensive care, you will be transferred to another area of the hospital where you will be able to rest better. You will begin walking and your recovery will continue until your discharge home. As your recovery progresses, you will require less medication and in smaller doses.

Your chest incision may have been closed with either stitches or staples. These will be removed about 7 to 10 days after the operation. You will probably be allowed to bathe or shower within a few days.

The rate of recovery is different for each person, but you will continue to progress and notice improvement each day. Your physician, who closely follows your recovery, will determine the appropriate time for you to return home.

Moving Around

Follow your own physician and healthcare team's instructions with regard to the motions listed below; however, you may find the following hints helpful:

Getting Out of Bed

Roll onto your side and lower your legs off the bed as you push yourself to a sitting position using your upper body and arms.

Standing up From a Chair

Scoot yourself to the edge of the chair, position your feet under you, and stand using your leg muscles. Reverse to sit down.

Sitting

Sit with your back straight with both feet on the floor. Your knees should be level with your hips. Do not cross your legs or ankles.

Picking up an Item from the Floor

Do not bend at the waist. Bend at the knees and keep your back straight.

Returning Home

Your level of activity, diet, medication, and do's and don'ts will be fully reviewed by the healthcare team. Ask them any questions and follow their advice completely. Though everyone looks forward to going home, it is not uncommon to feel apprehensive about leaving the security of the hospital. A better understanding of what to expect when you go home will make it easier for you and your family to make the transition.

Successful heart valve surgery will improve your quality of life depending on your age, general health, and the condition of your heart. Your ability to follow medical advice, maintain an exercise program, and lead a healthy lifestyle are also important to your success. Gradually, you will begin to feel better and have more strength.

It is common that an echo cardiogram be obtained approximately 6 to 12 weeks after your surgery to obtain a baseline performance of your new prosthetic heart valve. This echo will provide baseline data for comparison against any future changes. Should any problems develop with a prosthetic heart valve, an echo test is the best and most readily available method of diagnosing any abnormalities. Often a comparison with the baseline echo will be valuable for early diagnosis. If your physician has not referred you for a baseline echo, be sure to ask if such a test would be desirable for you.

Problems are rare following heart valve surgery but sometimes do occur. You need to be aware of certain signs and symptoms that require immediate attention. If caught early, potential problems often can be easily corrected.

IF THE FOLLOWING SIGNS AND SYMPTOMS OCCUR, CALL YOUR PHYSICIAN IMMEDIATELY:

1. Chest pain or tight pressure that does not go away within a few minutes.
2. Sudden, severe or gradually increasing shortness of breath.
3. Temporary blindness in one eye or observing a gray curtain over an eye.
4. Weakness, clumsiness, or numbness of the face, arm, or leg on one side of your body even if only temporary.
5. Slurred speech, even if only lasts a short while.
6. Unusually rapid weight gain, retaining fluid, or swelling of the ankles (to monitor this, you should weigh yourself daily).
7. Loss of consciousness, even only if for a short time.
8. Fatigue, especially if accompanied with fever that does not go away in a few days (some physicians recommend you take your temperature twice daily for 2 to 3 weeks).
9. Any chills or fever above 100°F.
10. Unusual bleeding or bruising.
11. Stool that becomes dark or black, or dark urine. Always check for blood in urine or stool.
12. A sudden change or absence in the normal sound or sensation of your heart valve opening and closing, or in your heartbeat's rate and rhythm.
13. Redness, swelling, drainage, or discomfort around any incision.
14. Burning sensation or change in frequency of urination.

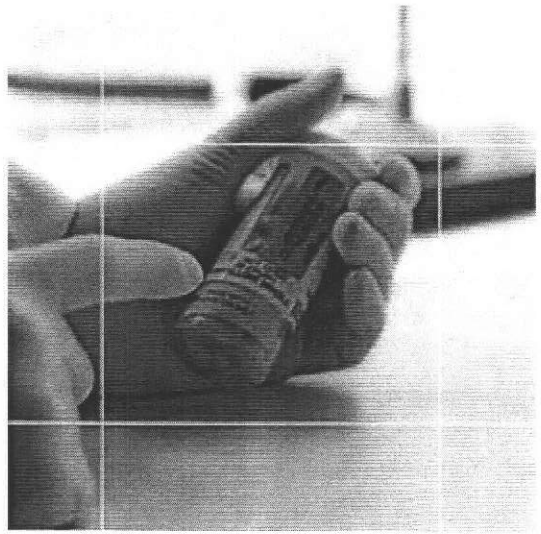
Medications

You should take only the medications that your physician has prescribed or approved. Over-the-counter drugs, such as aspirin, should not be taken without first checking with your physician.

If you have received a mechanical valve, medications called anticoagulants or "blood-thinners" (usually the drug is warfarin sodium) may be prescribed to prevent blood clots from forming.

These medications work by prolonging the time it takes for your blood to clot. Anticoagulants must be carefully monitored by taking a blood test called a prothrombin time (pro time) or an INR. Your physician will prescribe a dose to keep the pro time or INR within certain parameters. The medication is usually taken once daily. It should be taken at the same time each day. It is important to take this medication exactly as prescribed. Your physician also will tell you how often to have your pro time checked. From time to time your medication may need to be adjusted based on your test.

Anticoagulant medication limits your body's normal ability to stop bleeding. For this reason, you should be especially careful about activities that could produce cuts or bruises. Any blow to the head could cause serious injury. If this occurs, you should be observed carefully for the onset of dizziness, headache, weakness or numbness in an extremity, any change in vision, or unconsciousness. Call your physician with any concern you may have.

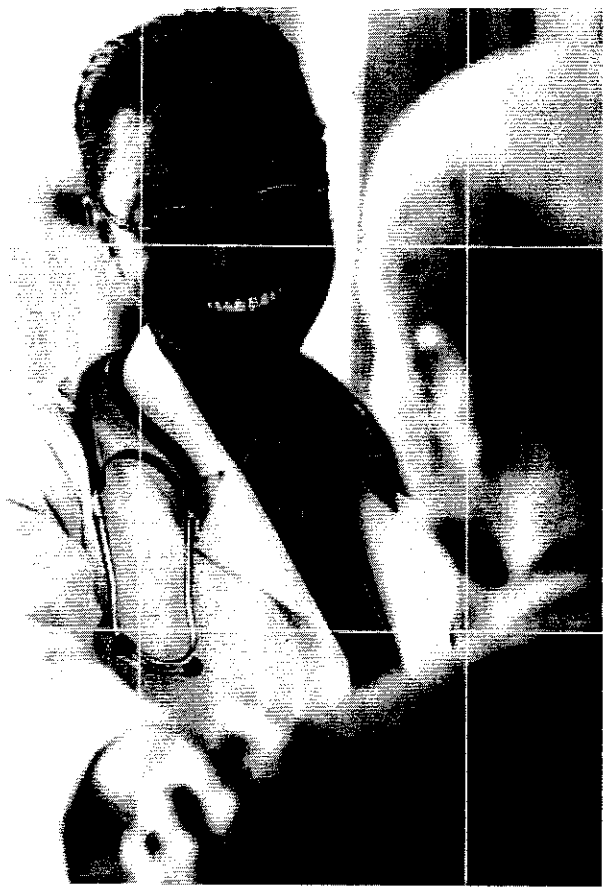


Anticoagulation Safety

If you are taking anticoagulants, you should tell your dentist or physician that you are taking anticoagulant medications. It is sometimes necessary to adjust the dosage or stop the medication before a procedure to prevent excessive bleeding.

Prevention of Infection

Talk with your physician or surgeon about the prevention of infection. In order to prevent infection it is important that you receive preventative antibiotic treatment before any dental work (including cleaning), any urinary procedure (such as cystoscopy), examination of the colon, or implantation of any other medical device. During these procedures, bacteria can be released into the bloodstream and cause an infection called bacterial endocarditis. Antibiotics are used to prevent this type of infection. Consult your physician if any signs of infection, including any superficial skin infections, should occur.



Magnetic Resonance Imaging (MRI)

The safety and effectiveness of Magnetic Resonance Imaging (MRI) examinations on patients with Carbomedics heart valve implants has been evaluated. All models of Carbomedics implantable products were tested, including mechanical heart valves, Mitroflow Aortic Pericardial Valve bioprostheses, the Carbo-Seal® valved conduits and annuloplasty repair rings. The largest and smallest sizes of each product were tested to bracket the masses and material quantities of the remaining sizes, providing a representational sample of the entire group.

The study found only minimal temperature changes and measurable deflection of any of the implants. Additionally, the study indicated that these devices should not disrupt the diagnostic use of MRI, unless the imaging area of interest is in the exact position of where the device is located.

Activity

Only your physician can advise you of your individual limitations. He or she is most knowledgeable of your general condition. However, basic guidelines for daily activity include the following:

Do not push or pull any heavy objects or lift anything weighing more than ten pounds for about six to eight weeks after surgery. This gives your breastbone enough time to heal.

Driving a Car

You should ask your physician to tell you when you can drive again. You should not try to drive unless you are very sure that you can do it safely. Riding as a passenger in a car is no problem. On trips of over one hour, stop and walk a short distance every hour.

Diet

Your physician or healthcare team may instruct you to avoid certain foods or add others to your diet. In general you should keep your weight in the normal range for your age and reduce the intake of salt. Good nutrition is important for your body to heal. Any major changes in your diet should be discussed with your physician or healthcare team.

Exercise

Do the amount and type of exercise your physician recommends. Exercise helps you recover your health and strength and can also help reduce stress.

Returning to Work

Most patients are able to return to work and usual activities. Your physician will advise you when you may return to work and any limitations that may be necessary.

Emotional Changes

Many people experience a period of depression or "let down" within a few days or even weeks following their surgery. It takes a lot of energy to deal with fear and anxiety and you may show your feelings more than usual. You may be tearful or cry and you may be irritable. Some people have bad dreams and others have a loss of memory or are unable to concentrate. These reactions are normal and usually pass within a few weeks. It may help to discuss these feelings with your family and physician.

Remember, undergoing surgery may be a stressful time. Following your physician's advice and openly discussing concerns with your family and healthcare team are positive ways to move toward recovery and your future.

FOR ADDITIONAL INFORMATION, YOUR LOCAL

AMERICAN HEART ASSOCIATION

HAS BOOKLETS ON DIET,

EXERCISE, SMOKING CESSATION,

AND MANY OTHER TOPICS.

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Important Data Sheet

This information should be carried with you at all times and be readily available to family and co-workers.

	Name	Telephone
Personal physician		
Cardiologist		
Surgeon		
Hospital (Emergency)		
Names of Medications		

Date of valve implant _____

Valve type, position, and serial number _____

Questions for My Physician

Questions for My Physician

Heart Valve Surgery

CAUTION

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

Please consult with your physician if you have any questions regarding the warnings and precautions associated with this valve or any prosthetic heart valve.

Customer Service

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