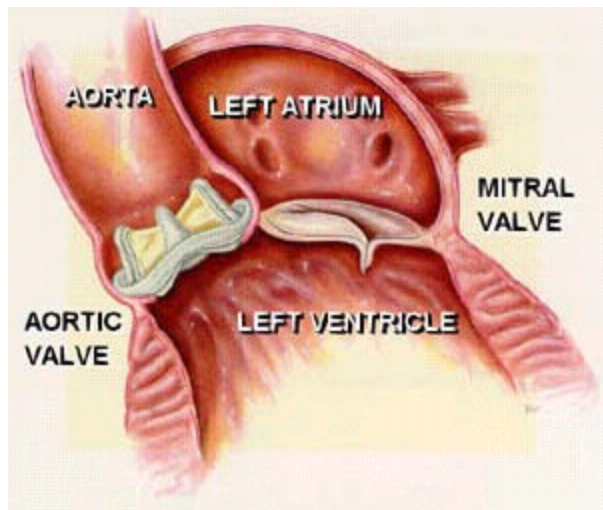


## Cedars-Sinai Medical Center Prosthetic Heart Valve Information



The following pages contain information on artificial heart valves including photos and characteristics of different types of heart valves, links to manufacturers, anticoagulation protocols, echocardiographic and hemodynamic data, durability/outcome data, and protocols for thrombolytic therapy of heart valves. Please keep in mind that this page is still a work in progress. All medication doses and recommendations should be checked for accuracy against original sources.

### Types of Prosthetic Valves

#### Mechanical Valves

- **Ball Valves.** Ball valves were the first valves implanted in humans. A variety of designs were attempted over the years. The only ball valve still implanted in the United States is the Starr-Edwards valve.
- **Disk Valves.** Disk valves can have either one or two leaflets and are therefore described as either single or bileaflet valves. The earliest designs had a single leaflet and were very successful. Although the development of the bileaflet valve occurred later, bileaflet valves currently dominate the mechanical valve market with a 90% market share in the U.S.
  1. Single Leaflet Disk Valves. The most historically important single leaflet valve was the original Bjork-Shiley valve. Although this valve is no longer sold in the United States it was a very successful and durable design. The single disk valves sold in the United States currently include the Medtronic-Hall valve and the Omniscience valve.
  2. Bileaflet Disk Valves. The prototypical and by far the most successful bileaflet valve is the St. Jude valve. The St. Jude valve has spawned many imitators but currently remains solidly in the lead in mechanical valve implantations in the United States. Other bileaflet valves include the Carbomedics valve and the Edwards-Duromedics valve which is no longer available in the United States.

#### Tissue Valves

- Animal Tissue Valves (xenografts, heterografts). Animal tissue valves are called xenografts from the Latin prefix "xeno-" for foreign or heterografts. Xenografts can be of valve tissue, typically porcine or pig valve tissue; or they can be of non-valve tissue, for example bovine or cow pericardium.
- Human Tissue Valves (homografts, autografts, Ross Procedure). Human tissue transplants from another person are called homografts and are similar to a valve transplant. An autograft is a valve

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moved from one position to another within the same patient or a valve self-transplant. The most common autograft procedure is moving the pulmonic valve to the aortic position, also called the Ross Procedure:

### References:

1. Morse D, Steiner RM, Fernandez J. Guide to Prosthetic Valves. Springer-Verlag New York.1985.
2. Baxter-Edwards Museum of Heart Valve Design

### Ball Valves

Ball valves consist of a ball in a cage and were the earliest design of heart valve to be used clinically. They remain one of the most reliable and durable designs available. Only one ball valve is still implanted in the United States, the Starr-Edwards valve.

- Starr-Edwards Valve
- Magovern-Cromie Sutureless Valve
- Smeloff-Sutter Valve

### Starr-Edwards Valve

The Starr-Edwards valve evolved through multiple models before essentially returning to its original simple design. Early variants tried to change the material the ball was made out of from rubber to metal and to cover the metal struts (the cage) of the valve with cloth. Unfortunately, these changes each caused their own problems. The cloth in the cloth covered models was thrombogenic, that is, it would cause blood clots to form, and would also fray and tatter over time.

The primary problem with the Starr-Edwards valve was that its hemodynamics were suboptimal. In order for the ball to occlude the valve when the valve shut, it had to be larger than the opening in the valve. This meant that there was a large ball in the middle of the blood stream that partially obstructed blood flow. Attempts to decrease the relative size of the ball led to later models.

### Starr-Edwards Model 1000

- Model: Starr-Edwards model 1000
- Type: Aortic caged ball
- Manufacturer: Baxter Healthcare, Edwards CVS Division, Santa Ana, CA
- Materials: Silastic ball, Cage-Stellite alloy No. 21, closed cage; sewing ring-Teflon
- X-ray: Three radiopaque metal struts join at top, ball radiolucent, cage radiopaque. Three metal "feet" project into center of orifice from ring.
- Dates: 1961-1966
- Available in US: Not at present

### Starr-Edwards Model 1200/1260

- Model: Starr-Edwards model 1200/1260
- Type: Aortic caged ball
- Manufacturer: Baxter Healthcare, Edwards CVS Division, Santa Ana, CA
- Materials: Silicone rubber ball with 2% barium sulfate, cage-Stellite alloy No. 21, closed cage; sewing

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ring-knitted Teflon and polypropylene cloth, no "feet."

- X-ray: Three radiopaque metal struts join at top, ball radiolucent, cage radiopaque
- Dates: 1966-
- Available in US: Yes

### **Starr-Edwards Model 2320**

- Model: Starr-Edwards model 2320
- Type: Aortic caged ball
- Manufacturer: Baxter Healthcare, Edwards CVS Division, Santa Ana, CA
- Materials: Ball-Hollow ball of radiopaque stellite alloy no. 21; Cage-Stellite alloy No. 21, struts covered with cloth (polypropylene over Teflon), closed cage; sewing ring-Teflon and polypropylene cloth
- X-ray: Three radiopaque metal struts join at top, ball radiopaque, cage radiopaque
- Dates: 1970-1976 (Discontinued) Est. 14,000 produced
- Available in US: No longer.

### **Starr-Edwards Model 2400 (Composite track)**

- Model: Starr-Edwards model 2400 (Composite track valve)
- Type: Aortic caged ball
- Manufacturer: Baxter Healthcare, Edwards CVS Division, Santa Ana, CA
- Materials: Ball-Haynes Alloy no. 21 (hollow), Cage-Stellite alloy No. 21 covered with cloth (Teflon/polypropylene), closed cage; sewing ring-Teflon/polypropylene
- X-ray: Three radiopaque metal struts join at top, ball radiolucent, cage radiopaque
- Dates: 1972-1981 (Discontinued)
- Available in US: No longer

### **Magovern-Cromie Sutureless Valve**

The Magovern-Cromie sutureless valve, as its name suggests, was designed to be implanted without using sutures. The valve had small hooks around its rim, which were angled to the side. The surgeon was to lower the valve into position and use the hooks to hold the valve in place.

- Model: Magovern-Cromie valve
- Type: Aortic caged ball
- Manufacturer: Coratomic, originally Surgitool, later Medical Engineering Corp.
- Materials: Ball-Silicone rubber with barium; cage-titanium; sewing ring; none. Cage open at top.
- X-ray: Cage radiopaque, open at top, ball radiopaque, hooks protrude from base ring.
- Dates: 1963-xxxx

### **Smeloff-Sutter Valve**

One obvious approach to designing a ball valve with less obstruction to flow was to shrink the size of the ball. However, if the ball is made smaller than the hole in the valve, it needs to be restrained on both sides of the valve with a cage so that it does not pop back through the hole and leave the valve. The Smeloff-Sutter and Cutter-Smeloff valves were designed to provide better hemodynamics by shrinking the size of the ball and providing a smaller cage on the entry side of the valve to restrain the ball.

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- Model: Smeloff-Sutter valve
- Type: Aortic, mitral, tricuspid caged ball
- Company: Sutter Biomedical Inc.
- Materials: Ball-Silicone rubber; cage-titanium; sewing ring-Teflon
- X-ray: Radiolucent ball, 3 struts from both top and bottom of valve, open cages on both sides, inflow cage smaller than outflow.
- Dates: 1966-xxxx (Discontinued).
- Potential Problems: Ball variance, swelling of ball from lipid absorption, can cause sticking of ball in inflow orifice.

### Single Leaflet Disc Valves

Single leaflet disk valves currently form a small part of US mechanical heart valve implants. The most commonly implanted single leaflet valve in the US at present is the Medtronic-Hall valve.

- Beall Valve
- Bjork-Shiley Valves
- Cooley-Cutter Aortic Valve
- Cross-Jones Valve
- Gott Daggett Valve
- Harken Valve
- Kay-Shiley Valve
- Lillehei-Kaster
- Medtronic-Hall Valve
- Omniscience Valve
- Starr-Edwards Disc Valves
- Ultracor Heart Valve
- Wada Cutter Valve



### Beale Valve

The Beall Model 106 was a caged disc valve.

- Materials: Disk, pyrolitic carbon; cage, pyrolitic carbon; sewing ring, Dacron.
- Manufacturer: Coratomic
- X-ray Appearance: Two parallel bars attached to an indented opaque ring with four struts, disk is radiopaque.
- Date of Manufacture: March 1974 - (not currently available)

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**Bjork-Shiley Valve**

The Bjork-Shiley valve is one of the most successful single disk valves ever made. Tens of thousands were implanted in the United States. The original model of the Bjork-Shiley valve was an extremely reliable and durable valve. It had good hemodynamics and a low rate of thromboembolism. The Bjork-Shiley valve is a tilting disk valve with a single disk. The disk is held in place by an inflow and an outflow strut.

Unfortunately, attempts to improve the hemodynamics of the original Bjork-Shiley valve by redesigning it led to disaster (see the Convexo-Concave story below). Certain models of the Bjork-Shiley valve developed strut fractures resulting in embolism of the disk. This led to all models of the Bjork-Shiley valve being removed from the United States valve market. Currently, the Bjork-Shiley monostrut valve is still sold in Europe and outside the United States. It should be emphasized that most models of the Bjork-Shiley valve are extremely durable and have very low (nearly zero) rates of structural failure.

**Identification of Bjork-Shiley Valves:**

The greater incidence of strut fractures in certain models of Bjork-Shiley valves makes it important for physicians to be able to identify which model Bjork-Shiley valve the patient has. This can be determined from the serial number of the valve. The model at greatest risk is the 70o CC valve. CC Stands for Convexo-concave.

The serial number is constructed from the sewing ring size + the letter code + 6 digit number.  
 Example: 27MBCA1234 = Size 27 mitral 70o CC valve with subannular sewing ring.

<b>Model Codes for Bjork-Shiley Valves</b>				
		Mitral	Mitral	Mitral
<b>Model</b>	<b>Aortic</b>	<b>Sub</b>	<b>Supra</b>	<b>Intra</b>
Delrin Disc	AB	MB	MBR	MBU
Conical/Spherical	ABP	MBP	MBRP	MBUP
60oConvexoconcave	ABC	MBC	MBRC	MBUC
70o Convexoconcave	ABCA	MBCA	MBRCA	MBUCA
70o Convexoconcave	ABCB	MBCB	MBRCB	MBUCB
Monostrut	ABM	MBM	MBRM	MBUM



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**BJORK-SHILEY STANDARD VALVES:**



- Bjork-Shiley Aortic Valve
- Bjork-Shiley Valve



- Bjork-Shiley Valve with Delrin Ring

The original Bjork-Shiley valve was a single disk valve in which two small C-shaped metal struts held the disk in place. The valve was implanted in many patients here in the United States and across the world. The valve gained a reputation for excellent durability over the years.

**Bjork-Shiley Aortic Standard**

- Model: Bjork-Shiley standard
- Type: Aortic tilting disk
- Manufacturer: Shiley Inc.
- Materials: Disk-Pyrolytic carbon or Delrin (pre-1972); cage-Haynes 25; sewing ring-Teflon
- X-ray: Cage radiopaque with two roughly C shaped struts that project into orifice, disk radiolucent except for a thin radiopaque rim since 1975. Opens to 60 degrees, closes to 0 degrees. Serial numbers with 5 digits have radiopaque discs, 4 digit SN have radiolucent disks.
- Dates: Delrin disk-1969-1971; Pyrolytic carbon after 1971, marker ring in disk after 1975, Convexo-concave disk after 1979. (Valve is currently discontinued)
- Durability: Estimated Mean Time Between Failures=650 for Conical Disk, 12,080 for spherical disk
- Serial Numbers: 17ABPxxxx to 33ABPxxxx . ABP in SN denotes standard disk. First 2 digit represent valve size (ie 17mm).

**Bjork-Shiley Mitral/Tricuspid Standard**

- Model: Bjork-Shiley standard
- Type: Mitral/tricuspid tilting disk
- Manufacturer: Shiley Inc.
- Materials: Disk-Pyrolytic carbon or Delrin (pre-1972); cage-Haynes 25; sewing ring-Teflon
- X-Ray: Cage radiopaque, with two roughly C shaped struts that project into orifice; disk radiolucent except for a thin radiopaque rim since 1975. Opens to 60 degrees, closes to 0 degrees. Error of 15 degrees may be seen in estimating motion.
- Dates: Delrin disk-Since 1971; Pyrolytic carbon after 1972, marker ring in disk since 1975 (Valve is

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currently discontinued).

- Serial Numbers: 3 models with differing sewing rings. Subannular ring-17MBPxxxx to 33MBPxxxx; Supra-annular ring- 17MBRPxxxx-33MBRPxxxx; Intra-annular suture ring-17MBUPxxxx - 31MBUPxxxx. First 2 digit represent valve size (ie 17MBPxxxx = 17mm valve)

**BJORK-SHILEY CONVEXO-CONCAVE MODELS:**



- Bjork-Shiley Convexo-Concave Aortic Valve



- Bjork-Shiley 60 Convexo-Concave Mitral valve



- Bjork-Shiley Aortic Supraannular valve



- BS Convexo-Concave UR valve

Unfortunately, in an attempt to improve on the original valve, modifications were made to the valve to increase the opening angle of the disk and to reshape the disk to allow better flow. These models were called the 60-degree and 70-degree Convexo-concave models. Some of these Convexo-Concave models later developed cracks in the C-shaped, metal outflow struts holding the disk in place. Eventually, the struts would fail and the disk would escape from the valve. The patient would then become gravely ill and could die from leakage of blood back through the valve. The manufacturer of the valve was originally Shiley Laboratories. Shiley was purchased by Pfizer, a large pharmaceutical company, however, and now Pfizer has unwittingly taken on a potentially enormous liability risk. A law suit has already been settled calling for the expenditure of funds by Pfizer to develop methods to detect and prevent Bjork-Shiley CC strut fractures.

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Analysis of the broken ends of the struts from patients with strut fracture revealed that one end of the strut was worn smooth while the other end was jagged. This meant that one side of the strut broke first and then was worn smooth rubbing against the housing of the valve until the second strut broke. Therefore, there is a window of time between when one end of the strut breaks and when the strut completely breaks off during which it might be possible to detect impending strut failure.

Considerable work has been expended in attempting to find ways to detect whether the strut has broken. Computer analysis of high resolution X rays of the valve has shown promise, but is an expensive technique. Currently, the recommendation is that patients with these valves not have them removed prophylactically. The reason is that it appears that the risks of death from the valve strut breaking are less than the risk of death from a repeat surgery. The risks of a strut breaking are higher for certain subgroups, however. For example, people with larger (33mm) mitral valves appear to be at the highest risk of breakage. In general, people with the largest valves seem to be at higher risk as do people with the valve in the mitral position.

### **Bjork-Shiley Aortic Convexoconcave Valve**

- Model: Bjork-Shiley convexoconcave
- Type: Aortic tilting disk
- Manufacturer: Shiley Inc.
- Materials: Disk-Pyrolytic carbon; cage-Haynes 25; sewing ring-Teflon
- X-Ray: Cage radiopaque with two roughly C shaped struts that project into orifice, disk has a thin radiopaque rim. Opens to 60 degrees, closes to 0 degrees.
- Dates: 1975- xxxx (Valve is currently discontinued)
- Durability: Estimated mean time between failures varies with valve size, location, manufacturing lot. Overall estimates:
  - BS 60° CC: MTBF=13\*
  - BS 70° CC: MTBF=2\*
- Serial Numbers: 21ABCxxxx to 33ABCxxxx . ABC in SN denotes Convexoconcave disk. First 2 digit. See table at top of this topic for full serial number information. represent valve size (ie 17mm).

### **Bjork-Shiley Mitral/tricuspid 60 Degree Convexoconcave Valve**

- Model: Bjork-Shiley convexoconcave
- Type: Mitral/tricuspid tilting disk
- Manufacturer: Shiley Inc.
- Materials: Disk-Pyrolytic carbon; cage-Haynes 25; sewing ring-Teflon
- X-Ray: Cage radiopaque with two roughly C shaped struts that project into orifice, disk has a thin radiopaque rim. Opens to 60 degrees, closes to 0 degrees.
- Dates: 1975- xxxx (Valve is currently discontinued)
- Estimated mean time between failures varies with valve size, location, manufacturing lot. Overall estimates:
  - BS 60° CC: MTBF=13\*
  - BS 70° CC: MTBF=2\*

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- Serial Numbers: Three models with differing sewing rings. Subannular ring-17MBCxxxx to 33MBCxxxx; Supra-annular ring- 17MBRCxxxx-33MBRCxxxx; Intra-annular suture ring- 17MBUCxxxx -31MBUCxxxx. First two digit represent valve size (ie 17MBCxxxx = 17mm valve)

### Bjork-Shiley Monostrut Valve

Still available in Europe and outside the United States. This valve has gained a good reputation for reliability and good hemodynamics. The disk is made of pyrolitic carbon, as are most current single and bileaflet disk valves. The outflow strut has been modified from the C-shaped, two strut design of the original and CC Bjork-Shiley models to be a single strut. The inlet and outlet struts are both part of the same piece of metal as the valve ring. Therefore there are no welds in the Monostrut as there were in the earlier B-S models.

### Bjork-Shiley Monostrut Aortic Valve

- Model: Bjork-Shiley monostrut
- Type: Aortic tilting disk
- Manufacturer: Shiley Inc.
- Materials: Disk-Pyrolitic carbon, cage-Haynes 25, sewing ring-Teflon or carbone-coated Dacron
- X Ray: Ring and struts radiopaque. Single strut on outflow side (instead of C shaped strut on other Bjork-Shiley disk valves) and C shaped inlet strut. Disk has radiopaque rim. Disk opens to 70 degrees
- Dates: 1981 to present. Not available in US but available in other countries.
- Durability: No fractures reported
- Serial Numbers: 17ABMSxxxx - 33ABMSxxxx

### Bjork-Shiley Monostrut Mitral/Tricuspid Valve

- Model: Bjork-Shiley monostrut
- Type: Mitral/tricuspid tilting disk
- Manufacturer: Shiley Inc.
- Materials: Disk-Pyrolitic carbon, cage-Haynes 25, sewing ring-Teflon or carbone-coated Dacron
- X Ray: Ring and struts radiopaque. Single strut on outflow side (instead of C shaped strut on other Bjork-Shiley disk valves) and C shaped inlet strut. Disk has radiopaque rim. Disk opens to 70 degrees
- Dates: 1981 to present. Not available in US but available in other countries.

### Cooley-Cutter Aortic Valve



- Type: Aortic caged disk
- Manufacturer: Cutter Biomedical Corp
- Materials: Disk is Pyrolite with tungsten insert, cage is titanium, sewing ring Teflon.
- X-Ray: Radiolucent disc enclosed by open ended cage with four struts (struts do not join in center)
- Date of Manufacture: Aortic: 1973-1978, Mitral 1971-1978 (discontinued)

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### Cross-Jones Valve

- Type: Caged Disk; Aortic, mitral and tricuspid valves
- Manufacturer: Pemco Inc.
- Materials: Silicone rubber disk reinforced with titanium ring, lens shaped; cage: titanium, sewing ring Teflon in early models, then Dacron.
- X-Ray: Radiolucent disk with a radiopaque outer ring. Three struts are visible which do not meet in center, open cage design.

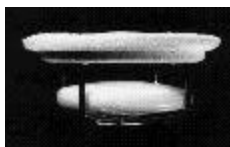
### Gott Daggett Valve

- Model: Gott Daggett
- Type: Hinged leaflet made of Dacron covered silicone rubber.
- Manufacturer: Daggett
- Materials: Leaflet: Dacron backed silicone rubber, cage: Graphite coated metal, sewing ring: Dacron
- X-Ray: Leaflets radiolucent, two opaque central cross struts, resembles a wagon wheel with 8 symmetrical inwardly facing spokes and a central cross bar that goes all the way across orifice.

### Harken Valve



- Harken Valve: Outflow view, closed



- Harken Valve: Side view, open



- Harken Valve: Oblique inflow view, open

The Harken valve consisted of a single disk in a metal wire cage. A number of Harken valves are still functioning 20 years after implantation. The disk of the Harken valve may occasionally show wear and on very rare occasions may escape. There is no reason to prophylactically remove these valves, however.

- Model: Harken P2 Prosthetic valve
- Type: Mitral caged disk
- Manufacturer: Medical engineering, originally Surgitek-Surgitool
- Materials: Disk Silicone; Cage: Titanium; sewing ring: Dacron

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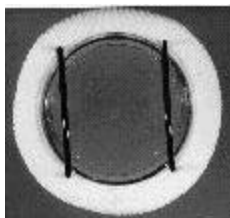
- X-ray: Radiopaque disk, lens shaped, four thin struts cross in middle, closed cage design.
- Dates: 1967-? (Discontinued)

### Kay-Shiley Valve



#### Kay-Shiley

- Models: Kay-Shiley
- Type: Mitral, Tricuspid caged disk valve with muscle guards
- Materials: Disk-Delrin; Cage-Haynes; Sewing ring-Teflon. Struts are uncovered, muscle guards covered.
- X-ray: Two thin sets of parallel struts for cage, four muscle guards set in two pairs and made of thin wire at 90 degrees to cage struts, disk is radiolucent.
- Dates: 1965-1980 (Discontinued)



#### Kay-Shiley K Series

- Models: Kay-Shiley K Series
- Type: Aortic and mitral/tricuspid caged disk valve with no muscle guards
- Materials: Disk-Silastic; Cage-Haynes 25; Sewing ring-Teflon. Struts are uncovered.
- X-ray: Two thin sets of parallel struts for cage, disk is faintly visible
- Dates: 1965-1968 (Discontinued)
- High incidence of thromboemboli

#### Kay-Shiley T Series

- Models: Kay-Shiley K Series
- Type: Aortic, mitral, tricuspid caged disk valve with no muscle guards
- Materials: Disk-Silastic; Cage-Haynes 25; Sewing ring-Teflon or dacron. Struts are uncovered.
- X-ray: Two thin sets of parallel struts for cage, disk is faintly visible
- Dates: 1967-1973 (Discontinued)

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**Kay-Shiley MGCD Series**

- Models: Kay-Shiley MGCD Series
- Type: Mitral caged disk valve with muscle guards
- Materials: Disk-Delrin; Cage-Haynes 25; Sewing ring-Teflon. Struts are uncovered, guards covered.
- X-ray: Two thin sets of parallel struts for cage, disk is faintly visible, two parallel bars surround 2/3 sewing ring to form muscle guards
- Dates: 1968-1980 (Discontinued)



**Kay-Shiley TGCD Series**

- Models: Kay-Shiley TGCD Series
- Type: Tricuspid caged disk valve with muscle guards
- Materials: Disk-Delrin; Cage-Haynes 25; Sewing ring-Teflon. Struts are uncovered, guards covered.
- X-ray: Two thin sets of parallel struts for cage, disk is faintly visible. Muscle guards of two sets of parallel bars on opposite sides of valve.
- Dates: 1968-1980 (Discontinued)
- High incidence of thromboemboli

**Lillehei-Kaster**

- Models: 500S (Mitral), 300S (aortic)
- Type: Aortic and mitral pivoting disk
- Manufacturer: Medical, Inc.
- Materials: Pyrolytic carbon over graphite disk, cage/ring: Titanium ASTM-F-67, sewing ring: Teflon
- X-ray: Radiopaque ring/housing gives rise to two curving wings, disk is only faintly radiopaque. Opens to 80 degrees from horizontal plane of ring, closes to 18 degrees from ring, total excursion of disk = 62 degrees.

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**Medtronic-Hall Valve**

The Medtronic-Hall valve is a unique single disk valve. The disk has a single hole in its center. This hole is used to mount the disk on a single, goose-neck shaped central strut and the disk rides up and down on the strut. A second, smaller strut stops the motion of the disk when fully open. This valve is extremely durable with an estimated mean time between failures in the thousands of years. Thromboembolic rates are low with this valve and the hemodynamics are as good as any single leaflet valve.

- Models: Medtronic-Hall A7700 (aortic), M7700 (mitral)
- Type: Aortic and mitral tilting disk
- Manufacturer: Medtronic Inc. Minneapolis, MN
- Materials: Cage: titanium, single block, computer machined; Disk: Pyrolytic carbon, sewing ring: knitted Teflon
- X-Ray: Radiopaque ring with large attached central curved strut and two smaller side struts. Center strut has bulge in middle, resembles goose-neck. Occluder is faintly radiopaque. Opening angle: 75 degrees for aortic, 70 degrees for mitral. Closing angle: 0 degrees.
- Date of Manufacture: 1977 to present
- Durability: Estimated Mean Time Between Failures = No MH fractures in model currently implanted in United States (non-D16 models). For D16 model: 1933\* (D16 model is not sold in US)

<b>Aortic Valve (Model A7700) Sizing Chart</b>			
<b>Size</b>	<b>Sewing Ring</b>	<b>Orifice</b>	<b>Orifice</b>
<b>Code</b>	<b>Diam (mm)</b>	<b>Diam (mm)</b>	<b>Area (cm<sup>2</sup>)</b>
20 AHK	20	16	2.01
21 AHK	21	16	2.01
23 AHK	23	18	2.54
25 AHK	25	20	3.14
27 AHK	27	22	3.80
29 AHK	29	24	4.52
31 AHK	31	24	4.52

Note: Measurements are those provided by the manufacturer in their product literature.

**Omniscience Valve**

The Omniscience valve consists of a uniquely shaped single tilting disc mounted in a metal housing. Although considerably less data is available on durability and thromboembolism rates with the Omniscience valve, it appears to have good durability and a reasonably low risk of thrombosis. It is a descendant of the discontinued Lillehei-Kaster disc valve. A variation, called the OmniCarbon valve, is made entirely of pyrolytic carbon.

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- Type: Aortic or mitral pivoting disk
- Manufacturer: Medical Inc.
- Materials: Disk: pyrolitic carbon; Cage: titanium, single piece; sewing ring: polyester knit fabric
- X-ray: Radiopaque ring and housing with two small projections from side, disk radiopaque, opens to 80 degrees, closes at 12 degrees from horizontal.
- Durability: No reported disc fractures.\*
- Dates: 1978-Present

### **Starr-Edwards Model 6500**

- Type: Mitral Caged disk
- Manufacturer: American Edwards Labs
- Materials: Stellite allow no 21 disk, cage Stellite Alloy no 21 struts, sewing ring: Teflon
- X-ray: Four metal struts crossing in center of orifice, four grouped elliptic holes on each half of valve base

### **Starr-Edwards Model 6520**

- Type: Mitral Caged disk valve
- Manufacturer: American Edwards Labs
- Materials: Disk: ultrahigh molecular weight polyethylene disk with embedded titanium ring, cage: Stellite alloy no 21, sewing ring: Teflon and polypropylene cloth
- Date of Manufacture: 1970-1976 (3,600 implanted) Discontinued
- X-ray: Radiolucent disk with radiopaque ring inside. Four struts intersecting. Radiopaque base ring.

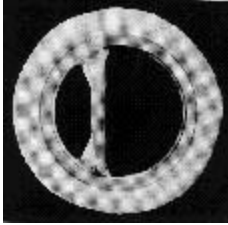
### **Ultracor Heart Valve**

The Ultracor valve consists of a single tilting disc mounted in a metal housing. The orifice ring is machined from a solid block of grade A-70 titanium without welds. Initial report in: J Heart Valve Disease 1998;7:647-654 reported on 446 patients receiving 499 Ultracor valves. 225 AVR, 172 MVR, 49 DVR. In 751 pt-yrs follow-up linearized complication rates were AVR-2.1, MVR-4.0, and DVR-4.0. TE rates were 0.1, 3.0, and 0.8 for AVR, MVR, DVR respectively. No structural failures were seen. Overall actuarial freedom from TE at 5 years were 99% for AVR, 88% for MVR.

Ref: Li H, Jeffrey R, Davidson K, et al. J Heart Valve Disease 1998;7:647-654

- Type: Aortic or Mitral pivoting disk
- Sizes: Aortic- 19, 21, 23, 25, 27, 29 mm (sewing cuff diam); Mitral 23, 25, 27, 19, 31, 33mm (sewing cuff diam).
- Manufacturer: Aortech Europe Ltd. Strathclyde Business Park, Lanarkshire, Scotland, U.K. Tel: +44(0)1698 746699. Fax: +44 (0) 1698 748474
- Materials: Disk: Pyrolite carbon coating on a tungsten-impregnated graphite substrate; Cage: titanium, single piece; sewing ring: knitted Teflon®. Rotatable housing
- X-ray: Radiopaque ring and housing with two small projections from side and large central strut, disk radiopaque (?), Aortic valve opens to 73 degrees, Mitral valve opens to 68 degrees. Both valves close at 0 degrees.
- Durability: No reported disc fractures.
- Dates: Initial clinical implants began 1984. Obtained CE Mark in 1995

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**Wada Cutter Valve**

Perhaps one of the most unique, even stylish, valve designs, the Wada-Cutter valve was a single disk valve that had a disk shaped like a Star Trek flying saucer. Two metal struts at the sides of the valve housing held the disk in place. The design concept was to develop a pivoting, hingeless valve. The valve was developed at Sapporo Medical College Hospital by Dr. Juro Wada. The first total artificial heart implanted in 1969 by Dr. Denton Cooley used four Wada-Cutter valves.

- Manufacturer: Cutter Biomedical Corp.
- Materials: Poppet of PTFE (Halon), cage material: titanium, Sewing ring: Teflon.
- X-ray: Radiolucent poppet, small metal feet project into orifice of valve as hinges for disk.
- Dates of Manufacture: 1967-1972

\* Estimated Mean Time Between Failures (MTBF): in hundreds of years, from Grunkemeier et al. Prosthetic Heart Valve Performance: Long-term follow-up. Curr Prob Cardiol 1992;17:table 5, pg 357

**Bileaflet Disk Valves**

Possibly the first and, undoubtedly, the most successful bileaflet valve was the St. Jude valve. The widespread acceptance and large market share of the St. Jude valve has led to a host of competing bileaflet valve designs. Most of these represent minor variations on the hinge system of the St. Jude valve. Perhaps the most unique of these competitors was the ill fated Medtronic parallel valve.

**ATS Bileaflet Valve**

- Manufacturer: ATS, Inc.
- Available in US: No. Undergoing trials outside of US. About 8,000 implants worldwide.
- Sizes:??
- Durability: Estimated MTBF ??
- X-ray Appearance:??

**Carbomedics Valve**

The Carbomedics valve is a bileaflet tilting disk valve made of pyrolytic carbon. This valve is being actively implanted in the United States although its market share is significantly less than the St. Jude valve. The Carbomedics CPHV Standard series valve was first implanted in 1986 and is rotatable and intra-annular. The Top Hat valve is a supra-annular model. The Orbis Universal valve has a sewing ring suitable for either aortic or mitral implantation. The Reduced valve is designed for the narrow aortic root and has a smaller sewing ring due to modification of the titanium stiffening ring.

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- Carbomedics Reduced Aortic Valve



- Carbomedics Mitral Valve



- Carbomedics TopHat Valve



- Carbomedics Standard Aortic Valve

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- Carbomedics Orbis Valve
  - Models: CPHV Standard Aortic and Mitral valves, R Series Aortic valve, Top Hat Supra-Annular aortic valve, and Orbis Universal Aortic/Mitral valve (not available in US)
  - Types: Bileaflet pyrolytic carbon valves. Mitral and aortic.
  - Manufacturer: Sulzer Carbomedics, Inc. 1300 East Anderson Lane Austin, Texas USA 78752. Phone: 512-435-3200. Fax: 512-435-3350
  - Available in US: Yes
  - Sizes: Aortic - 19 mm - 31 mm, Mitral - 21 mm- 33 mm; Pediatric 16mm-18mm
  - Durability: No fractures reported (270,000 implants)
  - X-ray Appearance: Single radio-opaque ring and tungsten content leaflets
  - MRI Compatibility: MRI imaging safe
  - Dates: 1986-present

**Edwards Duromedics Valve**

The Edwards Duromedics valve is a bileaflet valve that has been withdrawn from the market. It is no longer for sale in the United States.

- Model: Duromedics Bileaflet valves
- Type: Mitral and Aortic concave bileaflet valves
- Manufacturer: Originally Hemex Scientific, then Baxter-Edwards Inc.
- Materials: Housing- pyrolytic carbon over stellite ring for stiffening; disk-pyrolytic carbon over tungsten enriched graphite; sewing ring- Dacron coated or uncoated with Biolite
- Available in US: Not currently
- Sizes: Aortic, 19 mm - 27 mm; Mitral, 25 mm- 33 mm
- Durability: Disc fractures reported. Estimated mean time between failures=29\*
- X-ray Appearance: Ring is opaque, leaflets are faintly seen, best seen edge on like St. Jude leaflets.
- Dates: 1982-xxxx (Withdrawn from market)

**Medtronic Parallel Valve**

The Medtronic Parallel valve was a bileaflet valve with a uniquely designed pivot mechanism. The pivot allowed the leaflets to open to fully parallel. In contrast, the opening of the St. Jude valve leaflets is only to 85 degrees (therefore the two leaflets of the St. Jude valve form a 10-11 degree angle between them). In order to provide reliable closing of the leaflets, the pivot system allowed the leaflets to move along the axis of flow, partially out of the valve opening. When flow stopped and the backflow of blood carried the leaflets back down into the housing, they were deflected by the pivot mechanism causing the leaflets to

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begin rotating toward the closed position.

It was hoped that the fully parallel opening position of the leaflets would provide better hemodynamics with a lower pressure drop across the valve. Unfortunately, in its initial clinical trials in Spain, the valve demonstrated an increased incidence of thrombosis and was therefore withdrawn from the market. Medtronic is rumored to have a second bileaflet valve in the works as a successor.

- Manufacturer: Medtronic, Inc.
- Available in US: No. Trials in Europe halted due to thromboembolism/thrombosis
- Sizes: ??
- Durability: Estimated MTBF ??
- X-ray Appearance: ??

**On-X Valve**



A new pyrolytic carbon bileaflet valve in clinical trials in the United States and Europe. Implanted in the supra-annular position for aortic valve. Sewing ring is rotatable, reinforced by titanium rings. Pivot design allows some translational movement along flow streamline to provide a closing moment. Design provides for elongated and flared entry channel that may reduce vena contracta and entry turbulence. Hemodynamics appear one size better than SJ standard but this may be due to supra-annular sizing. A comparison to SJ HP series may be more equivalent.

- Model: On-X Valve
- Design: Mitral, aortic, tricuspid bileaflet valve
- Manufacturer: Medical Carbon Research Institute, LLC. 8200 Cameron Rd, St A-196, Austin TX 78754. Ph: 512-339-8000, FAX 512-339-3636.
- Materials: Cage-pyrolytic carbon; disk-pyrolytic carbon; sewing ring- Dacron fixed by titanium rings, rotatable
- Available in US: Only in clinical trials.
- Sizes: Aortic - 19 mm - 25 mm ?
- Durability: Not known yet.
- X-ray Appearance: Not known yet
- MRI Compatibility: MRI imaging safe but will not visualize valve due to titanium in sewing ring.
- Dates: 1996 to Present.

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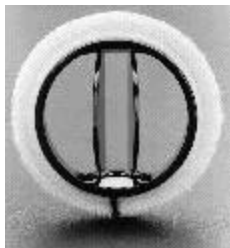


**St. Jude Valve**

- St. Jude Valve



- St. Jude Valve Inflow



- St. Jude Mitral Valve

The St. Jude valve has excellent durability, good hemodynamics and has gradually captured most (90%) of the U.S. mechanical valve market. It has a low thromboembolism and thrombosis rate and currently serves as the de facto gold standard against which all other prosthetic valves are judged. As of this year (1998), 20-year data is available for the St. Jude valve and will hopefully be presented at upcoming meetings.

Like all mechanical valves, the St. Jude valve requires lifelong anticoagulation. Early hopes that aspirin alone would be sufficient were proven wrong. Recent reviews and meta-analyses have shown that the St. Jude valve has demonstrably lower thromboembolic rates compared to ball valves. The thromboembolic rates are not clearly different between modern single disk valves and the St. Jude valve, however.

The standard St. Jude valve is implanted intra-annular in the aortic position and does not have a rotatable sewing ring. Recent additions to the St. Jude line have included the HP series, a supra-annular valve design and the HP Masters Series that includes a rotatable sewing ring. The X-ray appearance of the Masters Series valves is different. Due to 2 retainer rings and a helical spring in the sewing ring, X-rays now show a radio-opaque, circular metallic sewing ring.

- Models: St. Jude valve standard, HP series (supra-annular cuff), Masters Series (rotatable ring, supra-annular cuff)

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- Design: Mitral, aortic, tricuspid bileaflet valve
- Manufacturer: St. Jude Medical, Inc. , One Lillehei Plaza, St. Paul, MN 55117. Ph: 800-328-9634 (24 hr Technical/Professional Consultation). FAX: 612-482-8318
- Materials: Cage-pyrolitic carbon; disk-pyrolitic carbon; sewing ring-double velour knitted polyester. Standard and HP ring attached with sutures (non-rotatable), Masters Series attached with helical spring and two retainer rings and is rotatable.
- Available in US: Yes
- Sizes: Aortic, 19 - 25 mm; Mitral, 25 - 33 mm
- Durability: A few cases of disc fracture reported, most were probably due to surgical trauma during implantation. Estimated MTBF > 1,572\*.
- X-ray Appearance: The standard and HP St. Jude valves are only visible on chest X-ray if leaflets caught edge on. Otherwise they are not visible and are known on our X-ray rounds as the Stealth Valve. The new Masters Series valves have a metal spring and two metal retainer rings and are visible on X-ray as a circular metallic ring. For all models, the leaflets open to 85 degrees from horizontal. The angle between open leaflets should therefore be 10 to 11 degrees. When closed, the angle between leaflets should be 120 degrees
- MRI Compatibility: MRI imaging safe. Masters Series safe but probably cannot be visualized well on MRI due to metal in sewing ring
- Dates: 1977 to present.

\* Estimated Mean Time Between Failures (MTBF): in hundreds of years, from Grunkemeier et al. Prosthetic Heart Valve Performance: Long-term follow-up. Curr Prob Cardiol 1992; 17:table 5, pg 357  
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### **Animal Tissue Valves (Xenografts, Heterografts)**

The term xenograft denotes a valve made with tissue from an animal of a different species ("xeno" = foreign). The term heterograft means the same thing but the prefix comes from a different root, "hetero-" meaning "different." The most commonly used tissues are a) porcine (pig) valve tissue, and b) Bovine (cow) pericardial tissue .

### **Porcine Valves**

- Hancock Porcine Valve
- Carpentier-Edwards Porcine Valve
- Tissuemed Stented Porcine Valve

### **Pericardial Valves**

- Carpentier-Edwards Pericardial Valve
- Ionescu-Shiley Pericardial Valve
- Hancock Pericardial Valve

### **Stentless Valves**

- St. Jude Toronto SPV (Stentless Porcine Valve)
- Medtronic Freestyle Stentless Aortic Valve

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- Tissuemed Stentless Pulmonary Valve

### Porcine Valves

There are two major brands of porcine valve available today, Hancock and Carpentier-Edwards. Hancock valves are manufactured by the Hancock division of Medtronic Inc. Carpentier-Edwards valves are manufactured by the Edwards CVS division of Baxter Healthcare Inc.

### Hancock Porcine Valves

The Hancock porcine valve comes in two models, the standard Hancock valve and the Modified orifice valve. The standard valve is made from a single pig valve that is sewn onto a plastic stent. The base of the stent is then reinforced with a metal ring that is identifiable on x ray. The stent and reinforcing ring are covered with cloth (Dacron). The valve tissue is preserved with glutaraldehyde. The standard Hancock valve has been implanted since 1976 and has over 20 years of durability data.

The Modified Orifice (MO) version is a composite of two porcine valves. In the pig, (and indeed in all four-footed animals) one leaflet (the septal leaflet) of the aortic valve has muscle tissue growing into it making it stiffer than the other two leaflets. This stiffer leaflet frequently does not open fully and consequently in small sizes (19 to 21 mm) porcine valves can be moderately stenotic. In the Modified Orifice valve, this septal leaflet is replaced by a leaflet from another valve that has no muscle tissue in it. This allows more complete opening of all three leaflets of the valve. All 19 to 23 mm aortic valves are MO models.

The Hancock II valve is made using an anticalcification treatment, T6, which uses sodium dodecyl sulfate as a surfactant. In animal studies, this treatment has been shown to decrease mineralization of the valve leaflets. It remains unclear whether this treatment will increase the durability of these valves in humans.



### Hancock Model 242 Aortic Valve

- Model: Standard Hancock Model 242
- Type: Stented aortic porcine valve
- Manufacturer: Medtronic Inc. Minneapolis, MN. US Manufacturing plant in Irvine, CA
- Materials: Porcine aortic valve leaflets, glutaraldehyde processed, on a polypropylene flexible stent reinforced with a metal ring (Haynes alloy no. 25) at base; sewing ring- Polyester with silicone rubber insert
- Available in US: Yes
- Sizes: Aortic, 23 - 31 mm
- Durability: 10 years, 90%; 15 years, 50%.
- X-ray Appearance: Single round metal "O" ring.
- Dates: 1969 to present

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**Hancock Model 342 Mitral Valve**

- Model: Standard Hancock Model 342 and 342C
- Type: Stented mitral, tricuspid porcine valve
- Manufacturer: Medtronic, Inc., Minneapolis, MN. US Manufacturing plant in Irvine, CA
- Materials: Porcine aortic valve leaflets on a polypropylene flexible stent reinforced with a metal ring (Haynes alloy no. 25) at base; sewing ring- Polyester with silicone rubber insert (Model 342). Model 342C does not have silicone insert and has wider sewing ring.
- Available in US: Yes
- Sizes: Model 342: 25 mm - 35 mm
- Model 342C: 29mm- 31mm
- Durability: 10 years - 90%, 15 years - 50%
- X-ray Appearance: Single round metal "O" ring.
- Dates: 1969 to present

**Hancock Modified Orifice (MO) Valves**

- Model: Hancock MO Model 250H
- Type: Stented aortic porcine valve
- Manufacturer: Medtronic Inc. Minneapolis, MN. US Manufacturing plant in Irvine, CA
- Materials: Glutaraldehyde stabilized composite porcine aortic valve leaflets. Right coronary cusp leaflet of original porcine valve is replaced with a muscle free cusp from another valve. Leaflets are mounted on a polypropylene flexible stent reinforced with a metal ring (Haynes alloy no. 25) at base. Sewing ring material- Polyester
- Available in US: Yes
- Sizes: 19 - 25mm
- Durability: 10 years, 90%; 15 years, 50%
- X-ray Appearance: Single round metal "O" ring.
- Dates: 1969 to present

**Hancock II Valves**

Hancock II Aortic Valve

- Model: Model T505 Hancock II Aortic Valve
- Type: Stented aortic porcine valve
- Manufacturer: Medtronic Inc. Minneapolis, MN. US Manufacturing plant in Irvine, CA
- Materials: Porcine aortic valve leaflets treated with T6 antimineralization treatment. Process uses sodium dodecyl sulfate as surfactant. Delrin stent, reinforced with Haynes alloy no. 25 annulus ring

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and stent post markers. Sewing ring: Dacron

- Available in US: No
- Sizes: 21mm - 29mm
- Dates: Since 1982. Not currently available in US.

Hancock II Mitral Valve

- Model: Model T510 Hancock II Mitral valve
- Type: Stented mitral, tricuspid porcine valve
- Manufacturer: Medtronic Inc. Minneapolis, MN. US Manufacturing plant in Irvine, CA
- Materials: Porcine aortic valve leaflets treated with T6 antimineralization treatment. Process uses sodium dodecyl sulfate as surfactant. Delrin stent, reinforced with Haynes alloy no. 25 annulus ring and stent post markers. Sewing ring: Dacron with polyester felt suture ring insert.
- Available in US: No
- Sizes: 25 - 33mm
- Dates: Since 1982. Not currently available in US.

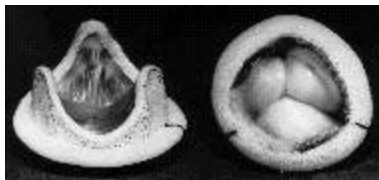
Hancock MO II (Modified Orifice II) Aortic Valve

- Model: Model 250HD Hancock II MO Aortic Valve
- Type: Stented aortic porcine valve
- Manufacturer: Medtronic Inc. Minneapolis, MN. US Manufacturing plant in Irvine, CA. Ph: 612-574-4000, 800-328-2518
- Materials: Composite design porcine aortic valve leaflets treated with T6 antimineralization treatment. Process uses sodium dodecyl sulfate as surfactant. Right coronary cusp of valve that has a muscle shelf is replaced with muscle free cusp from another porcine valve. Delrin stent, reinforced with Haynes alloy no. 25 annulus ring and stent post markers. Sewing ring: Dacron
- Available in US: No
- Sizes: 19 - 25mm
- Order Numbers: HA25019HD, ..., HA25025HD
- Dates: Not currently available in US.



**Carpentier-Edwards Porcine Valve**

- CE Porcine Aortic Valve Model 2625



- CE Porcine Mitral Valve Model 6625

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The Carpentier-Edwards (CE) Porcine valve is also made from a pig valve. The valve tissue is sewn to a metal wire stent that is bent to form three U-shaped prongs. A cloth (Dacron) sewing skirt is attached to the base of the wire stent and the stents are also covered with cloth. The valve has good durability data and good hemodynamics. Some surgeons prefer the CE Porcine and pericardial valves because of the material and design of the sewing ring. Note how the aortic sewing ring is saddle shaped and not flat as the Hancock valves sewing ring is.

- Model: Carpentier-Edwards porcine valve, model 6625 (mitral) or model 2625 (aortic)
- Type: Mitral and aortic porcine tissue valves
- Manufacturer: Baxter-Edwards Inc. US Manufacturing plant in Irvine, CA.
- Materials: Porcine valve tissue fixed in glutaraldehyde, stents made of wire, Elgiloy, which is a cobalt-nickel alloy; sewing ring-knitted Teflon
- X-ray Appearance: A continuous thin wire bent into 3 "U" shaped loops
- Available in US: Yes
- Sizes: Aortic, xx - xx mm; Mitral, 25 - 35 mm
- Durability: 10- and 15-year durability probably similar to Hancock valve.
- Dates: 1975 to present

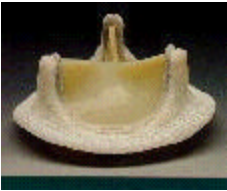
### Tissuemed Stented Porcine Valve

- Type: Porcine aortic and mitral stented valves
- Sizes: Aortic-20, 21, 23, 25, 27 mm external diameter; Mitral-25, 27, 29, 31, 33mm
- Manufacturer: Tissuemed Ltd. Astley Lane Industrial Estate, Astley Lane, Swillington, Leeds LS26 8XT. Tel: +44(0) 113 287 1122. Fax: +44 (0) 113 287 3087. E mail: [tissuemed@tissuemed.astra.co.uk](mailto:tissuemed@tissuemed.astra.co.uk)
- Materials: Porcine frame mounted valve. Porcine valve is low pressure (<2mmHg) glutaraldehyde fixed in 0.5% buffered glutaraldehyde. Stent material: (?). Sewing cuff: (?) .
- X-ray: (?)
- Durability: No data
- Dates: Initial clinical implants began 1979.
- Availability: CE Mark approved. Not available in US.

### Pericardial Valves

There are 2 pericardial valves that have been used in significant numbers of patients. The first of these was the Ionescu-Shiley pericardial valve, which is no longer available for implantation. The second, and currently used, valve is the Carpentier-Edwards Pericardial valve. Both of these valves are made from bovine (cow) pericardium.

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Carpentier-Edwards Pericardial Valve

CE Pericardial Valve

*Courtesy Baxter Healthcare Corp, Edwards CVS Division*

The Carpentier-Edwards (CE) Pericardial valve is the most recently approved tissue valve in the United States. It is manufactured from cow pericardium (bovine pericardium) which is mounted on wire stents similar to the Carpentier-Edwards Porcine valve. The only difference in the X-ray appearance is in the placement of the small metal cylinder, which joins the ends of the wire stent loop together. In the CE Pericardial valve, this cylinder is located in the middle of one of the stent post loops. In the CE Porcine valve, the post is located at the base of one of the loops.

The CE Pericardial valve has excellent hemodynamics, even in the smaller sizes (19mm and 21mm) and has gained a large market share (about 40% of US tissue valves) because of this advantage in the small aortic root. It has primarily displaced mechanical valves in this group of patients. A recent meta-analysis of durability data by Dr. Gary Grunkemeier demonstrates that the durability of the CE Pericardial valve is at least as good as standard porcine valves at 10 years. Longer term follow-up data will be required to determine if the CE Pericardial valve's durability is different from standard porcine valves.

The main factor limiting use of the CE Pericardial valve has probably been the legacy of the Ionescu-Shiley Pericardial valve implanted in the 1970s. Many older surgeons were stung by the early failure of the Ionescu-Shiley Pericardial valve (at six to eight years) and were reluctant to implant another pericardial valve. However, Baxter appears to have done an excellent job of analyzing the causes of failure of the prior pericardial valves and to have devised an ingenious method of securing the pericardial tissue to the stent posts to avoid the high stress regions that led to tears in the Ionescu-Shiley pericardial valve (see diagram).

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### CE Pericardial Design Features

*Courtesy Baxter Healthcare Corp, Edwards CVS Division*

- Manufacturer: Baxter Healthcare Corporation, Edwards CVS Division. US Manufacturing plant in Irvine, CA.
- Available in US: Yes
- Sizes: Aortic, 19 - 27 mm; mitral, not available yet. Some surgeons have implanted large aortic valves in the mitral position but this is discouraged by the manufacturer.
- Durability: At 12 years, Freedom from reoperation = 89%; Freedom from explant due to valve dysfunction = 91%
- X-ray appearance: A continuous thin wire bent into three U-shaped loops

### Ionescu-Shiley Pericardial Valve

The Ionescu-Shiley (I-S) Pericardial Valve had excellent hemodynamics with gradients significantly below the competing porcine valves of the time. However, the valve also tended to fail prematurely, with significant numbers of failures becoming evident by six years after implantation. The time lag before the realization that these valves had accelerated degeneration led to significant numbers of these valves being implanted. Many surgeons became reluctant to implant pericardial valves after the experience of having to reoperate on these patients.

- Model: Ionescu-Shiley Standard Pericardial Xenograft
- Type: Aortic, mitral, bovine pericardial tissue
- Manufacturer: Shiley, Inc.
- Materials: Stent-titanium covered with Dacron; Leaflets-3 cusps of glutaraldehyde treated bovine pericardial tissue.
- X-ray: Radiopaque three pronged stent with three holes in each stent and evenly spaced holes at base of stent.
- Dates of Manufacture: 1976- xxxx. (Discontinued)
- Durability: Six to eight years

### Hancock Pericardial Valves

These are discontinued models.

Aortic Hancock Pericardial Valve

- Model T405 - Hancock pericardial aortic valve

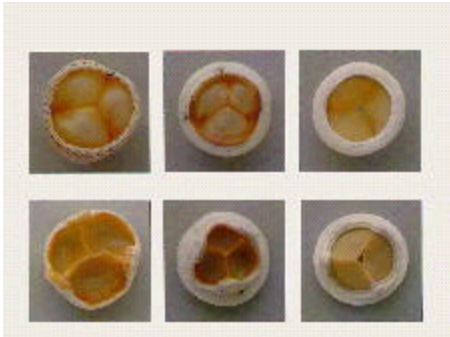
Mitral Hancock Pericardial Valve

- Model T410 - Hancock pericardial mitral valve

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### Stentless Valves

The plastic or metal stent in stented valves takes up some of the room available for blood flow through the valves. Theoretically, by removing the stents and eliminating the sewing skirt, more area would be available for flow through the valve resulting in improved hemodynamics.



Stentless./Stented Porcine./Stented Pericardial valves

*Photo Courtesy of St. Jude Medical Inc.*

The search for improved hemodynamics has led to interest in stentless valves. Stentless valves are made by removing the entire aortic root and adjacent aorta as a block from the pig. The coronary arteries are tied off and the entire section is trimmed and implanted in the patient.

### St. Jude Toronto Stentless Porcine Valve (SPV)

*Photo Courtesy of St. Jude Medical Inc.*

The Toronto SPV was developed by Dr. Tyrone David in Toronto. The valve appears to have excellent hemodynamics and preliminary data demonstrates significant decreases in the thickness of the heart (regression of left ventricular hypertrophy) after the valve is implanted.

The primary drawbacks of the Toronto SPV is that the valve is more difficult to implant and requires special measurements for successful implantation. The operative time (and more importantly pump time and cross clamp time) are typically increased by a half hour, even in experienced hands. The valve is still too new to have good data on durability.

- Manufacturer: St. Jude Medical, Minneapolis, MN. Ph: 612-483-2000
- Materials: Porcine xenograft, polyester cloth covering.
- Design: No stent or sewing cuff. Inflow edge not scalloped., sinuses are scalloped.
- Available in US: Yes
- Sizes: Aortic, 19 - 29 mm
- Model Numbers: SPA 101-19, SPA 101-21,..., SPA-101-29
- Durability: Not known yet
- X-ray Appearance: Not seen on X-ray

### Freestyle Aortic Root Bioprosthesis

The Medtronic Freestyle valve is a stentless porcine valve that incorporates a "total root" design. Like other stentless valves, it appears to have excellent hemodynamics and demonstrates regression of left

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ventricular hypertrophy after implantation. The valve receives an antimineralization treatment to try to prevent calcification, similar to Medtronic's Intact bioprosthesis. The treatment is with a compound called alpha amino oleic acid (AOA), a derivative of oleic acid and was developed by Biomedical Design Inc., Atlanta. The valve is fixed in glutaraldehyde solution. The valve can be implanted in three basic ways:

1. As a full root replacement where the entire native aortic root and valve are removed and replaced with the Freestyle prosthesis
2. Using a subcoronary technique where the valve is used as a standard prosthetic valve would be. In this case the outflow portion of the valve must be sculpted to fit around the left and right coronary sinuses
3. Using a root inclusion technique where the Freestyle is implanted as a tube inside the native aorta.

The primary drawbacks of the Freestyle stentless valve are similar to the Toronto SPV (see above): the valve is more difficult to implant and requires special measurements for successful implantation. The operative time (and more importantly pump time and cross clamp time) are typically increased by a half hour, even in experienced hands. The valve is still too new to have good data on durability.

- Manufacturer: Medtronic Inc. Minneapolis, MN. Ph: 612-574-4000 or 800-328-2518
- Materials: Porcine xenograft, polyester cloth covering.
- Design: No stent or sewing cuff. Neither inflow edge or outflow edges are scalloped
- Available in US: Yes
- Sizes: Aortic, 19 - 29 mm
- Model Numbers:
- Durability: Not known yet
- X-ray Appearance: Not seen on X-ray

### Tissuemed Stentless Pulmonary Valve

- Type: Porcine pulmonary stentless valve
- Sizes: 19, 20, 21, 23, 25, 27, 29mm external diameter
- Manufacturer: Tissuemed Ltd. Astley Lane Industrial Estate, Astley Lane, Swillington, Leeds LS26 8XT. Tel: +44(0) 113 287 1122. Fax: +44 (0) 113 287 3087. E mail: [tissuemed@tissuemed.astra.co.uk](mailto:tissuemed@tissuemed.astra.co.uk)
- Materials: Porcine pulmonary stentless valve. Porcine pericardial sewing cuff. Low pressure (<2mmHg) glutaraldehyde fixed in 0.5% buffered glutaraldehyde.
- X-ray: Not visible
- Durability: No data
- Dates: Initial clinical implants began 1984. Obtained CE Mark in 1995
- Availability: CE Mark approved. Not available in US
- Human Tissue Valves (Homografts, Autografts, Ross Procedure)

### Human Tissue Valves

Human tissue valves can be of two types: a) homografts, which are valves transplanted from another person, or b) autografts, valves transplanted from one position to another within the same person. The most commonly performed autograft is the Ross Procedure, which involves transplanting the pulmonary valve to the aortic position.

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### **Homografts**

Homografts are valves transplanted from another human. A valve is removed from another person (after death) and transplanted into the recipient. There are no problems with rejection of the valve and patients do not require any type of immunosuppressive therapy.

Homograft valves are donated either by patients or by their families. The valves are then preserved in liquid nitrogen (cryopreserved) until needed. The valve must be thawed overnight before it is used. This means that a surgeon must know in advance what size and type of valve he is going to use.

Homograft valves tend to have good hemodynamics and good durability. It is not clear that either their durability or their hemodynamic performance is better than ordinary tissue valves. Homografts are also technically harder to put in for a surgeon than standard tissue valves such as the Hancock or Carpentier-Edwards valves. In addition, since the valve must be thawed overnight, the patient's valve size must be known before hand. This can be accomplished either through echocardiography or using Magnetic Resonance Imaging (MRI) scans.

As with heart transplants, homograft availability is limited by donor availability.

### **Autografts (Ross Procedure)**

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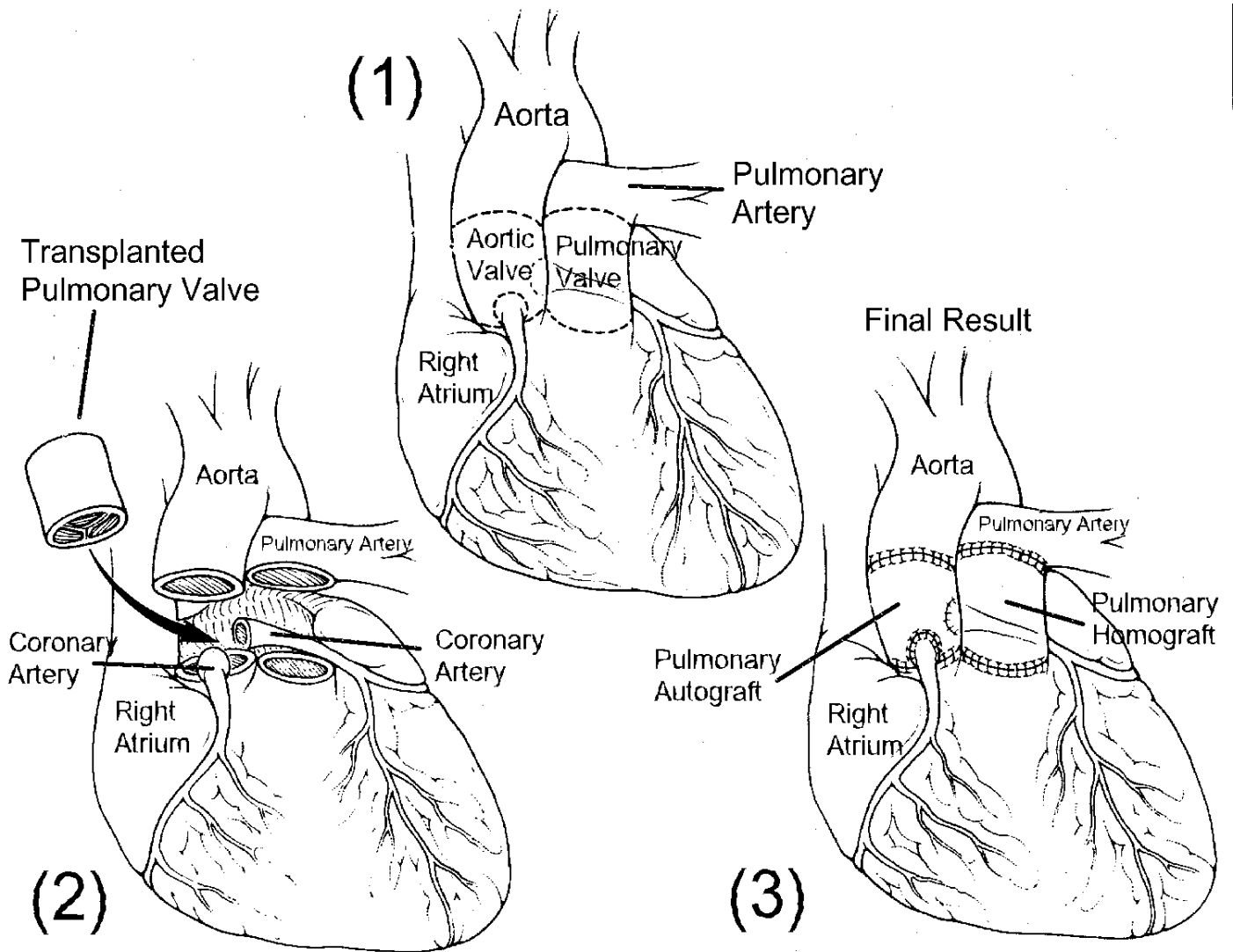


Figure adapted from: Kouchoukos et al, *New England Journal of Medicine*. 330(1):1-6, 1994 Jan 6.

Autografts are valves taken from the same patient in which the valve is implanted. The most common autograft procedure is the Ross procedure developed by Mr. Donald Ross (Mr. is an honorary title in Britain for physicians). The Ross procedure is used for patients with diseased aortic valves. The abnormal aortic valve is removed and the patient's own pulmonic valve is transplanted to the aortic position to take its place. A homograft pulmonic valve is then used to replace the patient's pulmonic valve.

**Advantages of Ross Procedure**

The main advantage of the Ross procedure is that the patient receives a living valve in the aortic position. The hope is that in children, the valve will continue to grow as the child grows older. Other potential benefits are better hemodynamics (there is essentially no pressure drop across the valve) and better durability. However it remains unclear whether the durability of the Ross is better than standard porcine

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or pericardial valves.

### **Disadvantages of Ross Procedure**

The Ross procedure is a very technically difficult procedure for the surgeon and involves considerable skill and time. The pulmonic valve must be sculpted to fit the aortic root and the pulmonary homograft must similarly be shaped to fit pulmonary root. Special measurements must be made to fit the transplanted pulmonic valve into the aortic root. There are many potential complications in less skilled hands, perhaps the commonest of which is leakage of the valve (aortic regurgitation). Many patients have small amounts of aortic regurgitation but some have moderate or even severe amounts and require a second operation for valve replacement. Other potential complications include stenosis of a coronary artery, right-sided endocarditis (since a prosthetic valve has now been implanted in the pulmonary position) as well as the usual complications of valve replacement.

### **Management of Anticoagulation in Patients Prosthetic Heart Valves**

There are several different schemes for anticoagulation of prosthetic valve patients.

### **American College of Chest Physicians Recommendations**

An issue of the journal, *Chest*, is published each year with the recommendations of the American College of Chest Physicians for anticoagulation. This is an excellent resource and is highly recommended. The most recent version was published in October, 1995. The reference for the prosthetic heart valve anticoagulation recommendations is: *Chest* 108;1995[Supp]:371S-379S.

The following recommendations follow the ACCP Guidelines:

#### **Mechanical Heart Valves**

- Use the INR (International Normalized Ratio) to follow anticoagulation
- Titrate the INR to 2.5-3.5
- All patients should receive lifelong anticoagulation with oral anticoagulants
- Concomitant use of aspirin is associated with an increased risk of bleeding but may reduce events
- Patients who have an embolic episode on adequate oral anticoagulation should receive additional aspirin or dipyridamole (Persantine)

#### **Bioprosthetic Heart Valves**

- Mitral bioprosthetic valve patients should receive three months of oral anticoagulants with the INR adjusted to 2.0-3.0
- Use of anticoagulation in aortic bioprosthetic valve patients in sinus rhythm is optional
- All patients in atrial fibrillation should receive oral anticoagulation (INR 2.0-3.0)
- Patients with a left atrial thrombus found at surgery should receive long term oral anticoagulation (INR 2.0-3.0)
- Patients in sinus rhythm should receive aspirin 325mg/day indefinitely (once warfarin is stopped)

#### ***New England Journal of Medicine* Prosthetic Valve Review Article**

Prosthetic heart valves. Vongpatanasin W, Hillis LD, Lange RA. *N. Engl J Med* 1996;335:407-416  
This recent review article on prosthetic valves presented recommendations for anticoagulation which

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differ from those published in *Chest* by the American College of Chest Physicians (ACCP) and commonly accepted. The major differences are in the anticoagulation recommendations for ball valves and dual valve patients where very high INRs are recommended and in single leaflet valves where slightly higher INRs are recommended.

It should be remembered that these recommendations are not based on prospective clinical trial data demonstrating that patients with these valves will do better with the listed INRs. They are based on the authors' opinions and on data from retrospective studies of event rates and anticoagulation levels. The higher INR for single leaflet valves compared to bileaflet valves ignores differences between single leaflet valves. Studies have shown that the newest generation single leaflet valves, such as the Medtronic-Hall valve, have low event rates even at lower INRs. Similarly, there are important differences in the thrombogenicity of ball valves. Models with cloth covered stents may have significantly higher thromboembolism rates.

<b>Antithrombotic Therapy for Prosthetic Heart Valve Patients</b>			
		INR (Warfarin)	Antiplatelet Therapy
Low	<b>Mechanical</b>		
	Caged-Ball	4.0-4.9	Not Indicated
	Single Disk	3.0-3.9	Not Indicated
	Bileaflet Disk	2.5-2.9	Not Indicated
	2 or more Valves	4.0-4.9	Not Indicated
High*	<b>Bioprosthetic</b>		
	Xenograft	2.0-3.0 x 3 months	Aspirin 325mg/d after
	Homograft	Not indicated	Not indicated
	<b>Mechanical</b>	3.0-4.5	Aspirin 80-160mg/d
	<b>Bioprosthetic</b>		
	Xenograft	2.0-3.0	Not indicated
	Homograft	2.0-3.0	Not indicated
*High Risk = LA clot		atrial fibrillation	prior embolism
			severe LV dysfunction

Source: *Prosthetic heart valves. Vongpatanasin W, Hillis LD, Lange RA. N. Engl J Med 1996;335:407-416*

#### Our Recommendations

- We would recommend use of the ACCP guidelines as a starting point:
- Mechanical Valves: INR=2.5-3.5
- Tissue Valves: INR 2.0-3.0 x 3 months followed by aspirin
- For bileaflet valves (St. Jude) and modern single leaflet valves (Medtronic-Hall), the lower end of this range should be used: INR=2.5-3.0.
- Mitral valve patients should probably be kept at the higher end of this range: INR=3.0
- Patients in atrial fibrillation should be kept at higher INRs: 3.0-3.5

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- For non-cloth covered ball valves and older disk valves the higher end of the range should be used: INR=3.0-3.5. Cloth covered or other known thrombogenic valves should be run at higher INRs, perhaps as high as INR=4.0-4.5.

### **Thrombolytic Therapy for Prosthetic Valve Thrombosis**

#### **Introduction**

Prosthetic valve thrombosis is an uncommon, but life-threatening complication after valve replacement. Both tissue valves and mechanical valves can develop thrombosis, but it is much more common for mechanical valves to develop obstructive thrombus than tissue valves.

#### **Tissue Valve Thrombosis**

I am only aware of a handful of cases of tissue valve thrombosis...but it does happen and is in the differential diagnosis of stenosis of a tissue valve. One should be most concerned about tissue valve thrombosis if a tissue valve appears to be stenotic early after surgery. This is one of the reasons that manufacturers recommend patients with tissue valves be anticoagulated for three months after valve replacement.

#### **Mechanical Valve Thrombosis**

Mechanical valves have a greater tendency to thrombose than tissue valves. Consequently, the literature on thrombolytic therapy for valve thrombosis has focused almost entirely on mechanical valves. Many reports have now appeared on the use of thrombolytic therapy in this setting and a representative set of references are listed at the bottom of this page.

#### **Thrombolytic Therapy for Thrombosed Prosthetic Valves**

The most important concept in using thrombolytic therapy for mechanical valve thrombosis is that of risk vs benefit. The treating physician must be aware of the major factors affecting the risk of thrombolytic therapy as well as those affecting the success rate for thrombolytic therapy.

##### **Factors Affecting Success of Thrombolytic Therapy**

- Valve Position: Aortic more successful, Mitral less successful.
- Valve Type: St. Jude bileaflet more successful, Ball and single leaflet less successful
- Amount of Clot Present: Large amount of clot lowers success rate
- Time to start of therapy: Longer time since onset of symptoms lowers success rate

##### **Factors Increasing Risk of Thrombolytic Therapy**

- Greater amount of clot: Not only a lower success rate, higher risk of embolism
- Mitral position: Higher risk embolism
- Single leaflet or ball valve: Higher risk of embolism
- Critically ill patients

#### **The Ideal Candidate for Thrombolytic Therapy**

From the above risk and benefit factors it becomes clear that the ideal candidate for thrombolytic therapy is a patient who meets the following criteria:

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- Aortic valve
- St. Jude Valve
- Recent onset of symptoms
- Small or no detectable clot on Transthoracic or Transesophageal echo, either on the valve or in the left ventricle or left atrium.

### Patient Status

The differences in reported mortality rates for thrombolytic therapy in different papers in the literature probably reflects differences in patient populations and in the philosophy of use of thrombolytic therapy. Most importantly, there are two distinct approaches to thrombolytic therapy: a) Elective thrombolytic therapy, and b) salvage thrombolytic therapy.

#### A. Elective Thrombolytic Therapy

Our own approach (1) is to use longer infusions of thrombolytic agents to achieve more gradual breakup of clot. Our published results have used 24 to 48 hour infusions of streptokinase or urokinase. This means that the patient must be stable enough to survive 24 to 48 hours before the valve is opened. Critically ill patients should therefore be taken to surgery if there is a significant risk of death within 24 to 48 hours. Thrombolytic therapy is used as an elective therapy.

#### B. Salvage Thrombolytic Therapy

The second school of thought uses thrombolytic therapy only in those patients "too sick" to go to surgery (3). In these centers, less sick patients are operated on and the most gravely ill are given thrombolytic therapy. Since thrombolytic therapy has a moderate risk of failure to restore function to the valve (about 15 to 25%), in our opinion, it seems unwise to wait unnecessarily before proceeding to definitive therapy, which is surgical re-replacement of the valve (or perhaps surgical declotting). The higher mortality associated with thrombolytic therapy reported in these series is probably due to this philosophy of use as a last resort.

### Regimines for Thrombolytic Therapy – Cedars-Sinai Medical Center Preferred Regimen:

1. Agent: Urokinase
2. Protocol: The protocol in the *Physician's Desk Reference* for administration of Urokinase for Pulmonary Embolism is followed.
3. Loading Dose: 4,400 U/kg given over 30 min
4. Maintenance Dose: 4,400 U/kg/hr as maintenance infusion x 12 to 24 hours
5. Followup: Cinefluoroscopy prior to initiating therapy and following morning
6. Termination of Therapy: With normalization of leaflet opening
7. Discontinuation of Therapy: Switch to IV Heparin 1,000U/hr titrated to PTT 70-100sec.
8. Conversion to PO Therapy: Convert to Coumadin after 24 to 48 hours of IV heparin

### References:

1. Silber H, Khan S, Matloff J, et al. The St. Jude Valve: Thrombolysis As The First Line Of Therapy For Cardiac Valve Thrombosis. *Circulation* 1993; 87:30-7
2. Kurzrok S, Singh AK, Most AS, Williams DO. Thrombolytic Therapy For Prosthetic Cardiac Valve Thrombosis. *J Am Coll Cardiol* 1987; 9:592-8

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3. Roudaut R, Labbe T, Lorient-Roudaut MF, et al. Mechanical Cardiac Valve Thrombosis: Is Fibrinolysis Justified? *Circulation* 1992; 86:Supp II: II-8-II-15
4. Kontos GJ, Schaff HV, Orszulak TA, et al. Thrombotic obstruction of disc valves: clinical recognition and surgical management. *Ann Thorac Surg* 1989; 48:60-5
5. Gueret P, Vignon P, Fournier P, et al. Transesophageal Echocardiography For The Diagnosis And Management Of Nonobstructive Thrombosis Of Mechanical Mitral Valve Prosthesis. *Circulation* 1995; 92:103-110
6. Martinell J, Jimenez A, Rabago G, et al. Mechanical Cardiac Valve Thrombosis: Is Thrombectomy Justified? *Circulation* 1991; 84:supp III:III-70-III-75
7. Reddy NK, Padmanabhan TNC, Singh S, et al. Thrombolysis In Left Sided Prosthetic Valve Occlusion: Immediate And Follow-Up Results. *Ann Thorac Surg* 1994; 58:462-71
8. Vasani RS, Kaul U, Sanghvi S, et al. Thrombolytic Therapy For Prosthetic Valve Thrombosis: A Study Based On Serial Doppler Echocardiographic Evaluation. *Am Heart J* 1992; 123:1575-80
9. Hurrell DG, Schaff HV, Tajik AJ. Thrombolytic Therapy For Obstruction Of Mechanical Prosthetic Valves. *Mayo Clin Proc* 1996; 71:605-13

### What's New in the Recent Literature

An intermittent survey of what's new and interesting in the literature on prosthetic heart valves. The selections are my own and therefore completely arbitrary and highly subjective. However, suggestions by e-mail are appreciated.

1. Hemodynamic assessment of Carbomedics bileaflet heart valves by ultrasound: studies in the aortic and mitral positions. Cap EG, Sung HW, Yoganathan AP. *Ultrasound in Med Biol* 1996; 22:421-30.  
An in vitro study of the correlation of Doppler ultrasound and catheter pressure gradients in the Carbomedics valve. Doppler ultrasound significantly overestimated gradients in aortic valves but not in mitral valves after correction for proximal flow velocities. The authors concluded that Doppler peak and mean gradients in Carbomedics valves should be interpreted with caution.
2. Failure of adjusted doses of subcutaneous heparin to prevent thromboembolic phenomena in pregnant patient with mechanical cardiac valve prostheses. Salazar E et al. *J Am Coll Cardiol* 1996; 27:1698-703.  
Report on 40 pregnancies in 37 patients with prosthetic heart valves treated with adjusted dose subcutaneous heparin (q8 or q6h) adjusted to PTT 1.5-2.5x control. Heparin was given in weeks 6-12 and in last two weeks of gestation. Incidence of spontaneous abortions was 37.5%, no warfarin embryopathy was seen. There was one maternal death from GI bleeding and two cases of fatal thrombosis of mitral disk valves during heparin therapy leading to termination of the study. The authors concluded that the regimen of subQ heparin used in this study was not effective in preventing prosthetic valve thrombosis.
3. Anticoagulation in pregnant women with prosthetic heart valves: a double jeopardy. Elkayam U. *J Am Coll Cardiol* 1996; 27:1704-6  
Excellent editorial by Dr. Elkayam reviewing new concepts in management of anticoagulation during pregnancy in women with prosthetic heart valves.  
Editorial Comment: Dr. Elkayam also has an excellent forthcoming book on heart disease and

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pregnancy, which discusses anticoagulation and prosthetic heart valve management during pregnancy. I recommend buying one copy for home and one for the office. I especially like the chapter on prosthetic valves and pregnancy by Elkayam and Khan.

4. Serial Doppler echocardiographic evaluation of bioprosthetic valves in the tricuspid position. Kobayashi Y, et al. *J Am Coll Cardiol* 1996; 27:1693-7  
Reported on 95 patients with tricuspid tissue valves, average follow-up 5.8 years. At 10 years only 46% were free of stenosis and 51% free of regurgitation. Stenosis and regurgitation began to be seen 1 to 2 years after TV replacement and 20/25 patients developed right heart failure. The authors conclude that the long-term durability of TV prostheses is substantially lower in their study than in prior studies.
5. In vitro endothelialization of bioprosthetic heart valves. Fischlein T, Fasol R. *J Heart Valve Dis* 1996; 5:58-65. Demonstrated that precoating tissue valves coated with factors to promote cell growth (fibronectin-heparin, acidic fibroblast growth factor, and angiogenic growth factor protein) promoted endothelial cell monolayer growth on valve leaflet tissue with lower deposition of calcium, magnesium and phosphate.  
Editorial Comment: The idea of promoting endothelialization of intravascular devices has been spectacularly successful with LVADS (see the Thermomedics HeartMate for example). There are several others also working on this concept including Dr. Viking Bjork. This is a technology to follow.
6. The cost of treating heart valve related complications. Caro JJ, et al. *J Heart Valve Dis*. 1996; 5:122-127.  
Estimates costs of managing different complications associated with prosthetic heart valves. Cost for managing valve thrombosis, endocarditis, non-structural dysfunction were all >\$30,000 per event. Management of embolism and hemorrhage were \$8,000 to \$11,500 per event, the costs of managing sequelae of an embolism was more than \$70,000 over 15 years.  
Editorial Comment: This paper provides an initial estimate of costs associated with events that are reported for heart valves and could provide a starting point for calculating the costs associated with different types of prostheses (tissue vs mechanical, etc).
7. Clinical experience with the first 100 ATS heart valve implants. Van Nooten et al. *Cardiovascular Surgery* 1996; 4:288-92.  
Describes the experience with 119 ATS valves in 100 patients: 61 AVR, 50 MVR, 8 TVR. Follow-up was five to 27 months. There was one in-hospital death, one death at three months, one embolic event nine days post op, and one prosthetic valve thrombosis in a tricuspid valve replacement which was successfully treated with thrombolytic therapy.  
Editorial Comment: It has been estimated that about 8,000 ATS valves have been implanted with about four years of follow-up data. There has been talk of using INRs as low as 1.0-2.0 with the ATS Open Pivot Standard Series valve but it is still premature to support this recommendation. In interpreting the results of the study of Van Nooten, one must be cognizant of the inclusion of 8 Tricuspid Valve replacements. In most series reporting outcomes in valves, outcomes are reported only for AVR, MVR and AVR+MVR patients. The inclusion of TVR patients in a study of a new mechanical valve will clearly increase the apparent rate of valve thrombosis. If large enough numbers of TVRs are put in, it may become difficult to determine if valve thrombosis or thromboembolism rates are truly lower for

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the ATS valves.

### New Valve Designs/Rumors

- Recent FDA Approvals (11/97)
- Medtronic Freestyle Stentless Valve
- St. Jude Toronto SPV Stentless Valve
- Alliance (Bjork-Shiley Monostrut) Valve
- ATS Medical
- Open Pivot Standard Series: A bileaflet valve. See above for story.
- AP Series: "Advanced performance" valve. No info
- Baxter
- Prima II: Stentless full root aortic valve with anti-mineralization treatment.
- Updated SAV: SAV may be enhanced with epoxy fixation instead of glutaraldehyde
- Pericardial: It is estimated that Pericardial valves may now account for 40% of all US tissue valves and 16% of all US valves of any kind.
- Carbomedics
- Photofix: A tissue valve made using a photo-fixation process and displayed at the AATS.
- Cryolife
- Mitral homograft: Multiple institutions in US are now doing mitral homografts (including CSMC). Appears to extend ability to repair valves instead of replacement.
- Bravo 300: Undergoing trials in Germany
- MCRI On-X Valve
- A new pyrolytic carbon bileaflet valve in clinical trials in the United States and Europe.
- Design: Implanted in the supra-annular position for aortic valve. Sewing ring is rotatable, reinforced by titanium rings. Pivot design allows some translational movement along flow streamline to provide a closing moment. Design provides for elongated and flared entry channel that may reduce vena contracta and entry turbulence.
- Hemodynamics appear one size better than SJ standard but this may be due to supra-annular sizing. A comparison to SJ HP series may be more equivalent.
- Manufacturer: Medical Carbon Research Institute, LLC. 8200 Cameron Rd, St A-196, Austin
- St. Jude
- Toronto SPV II: Utilizes antimineralization technology. Clinical trials in Canada to begin in October 1996
- Toronto SPV III: Utilizes antimineralization technology. Clinical trials in Canada to begin in October 1996
- Master Series: As of 2/96 about 3,000 Master Series implanted.