May 22, 2015 대한흉부외과학회 전공의 연수강좌, 강촌엘리시안

The Prosthetic Heart Valve

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“Not all innovations represent progress”

The feasibility of an operation is not the best indication for its performance.

BACKGROUNDS

Trends of Valvular Heart Surgery

Increased total number of VHD & VHS(intervention)

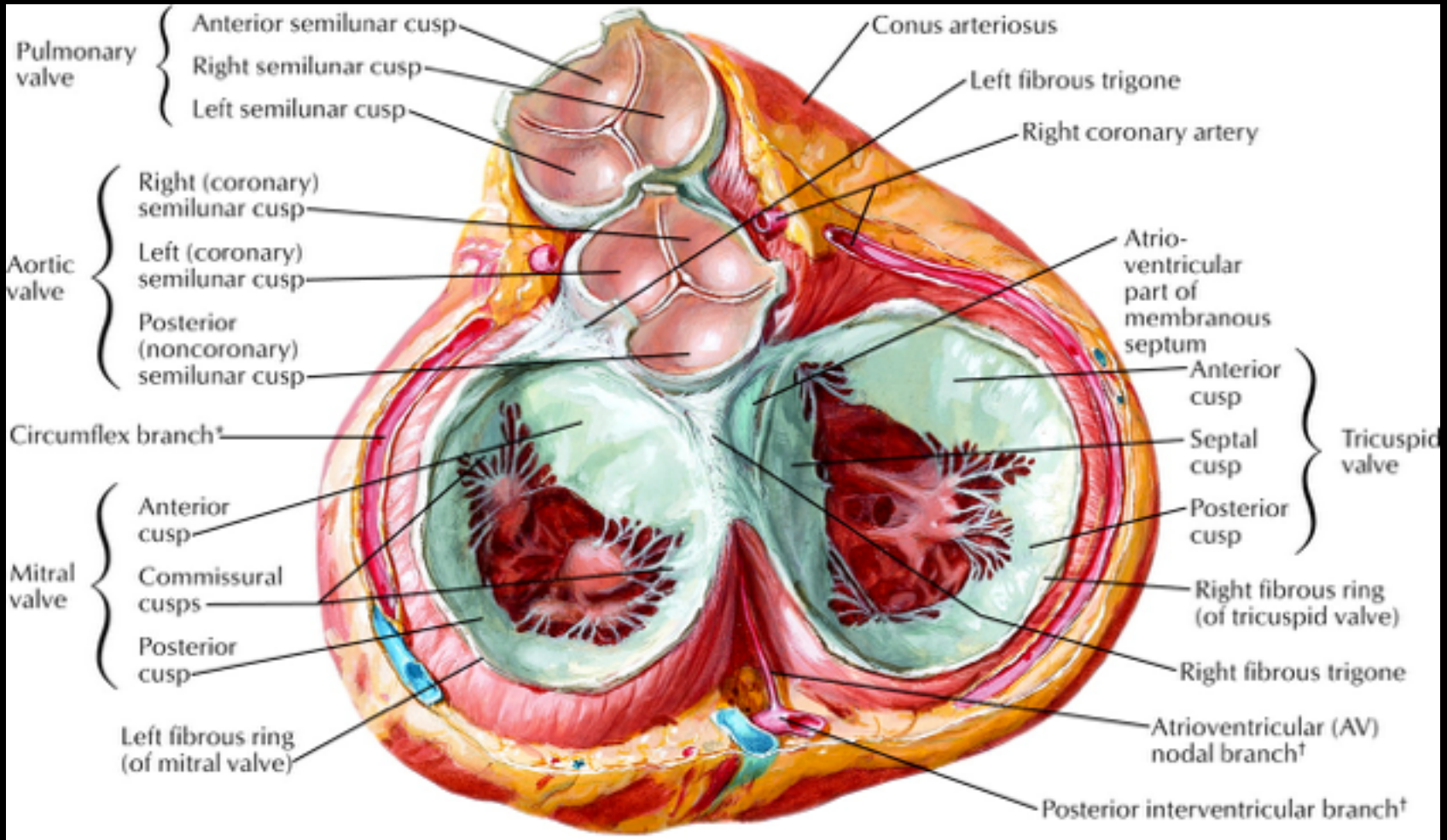
Decreased rheumatic VHD

Increased degerative VHD

Extended application of valve repair

Minimally invasive valve surgery

Normal Cardiac Valves



Heart in diastole: viewed from base with atria removed

BACKGROUNDS

Ideal Artificial Heart Valve

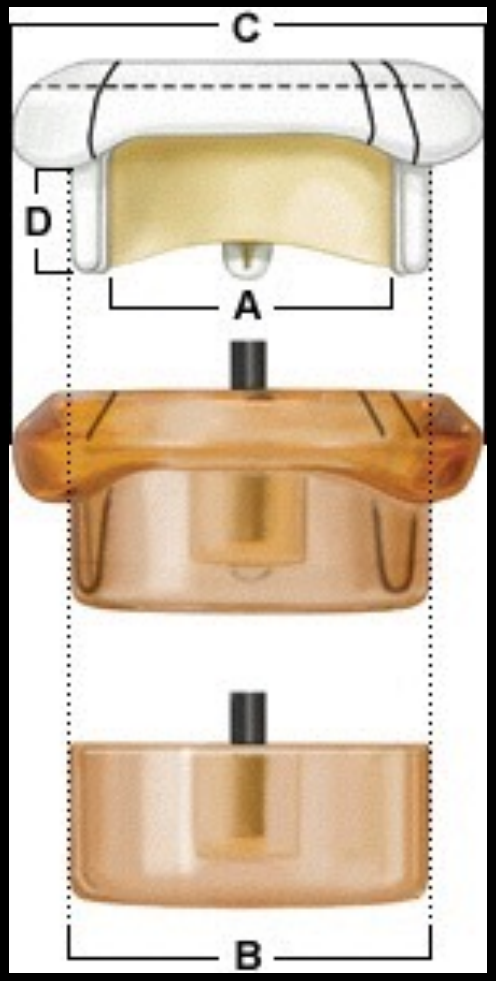
- ✓ Hemophilic (anti-thrombogenic)
- ✓ duration
- ✓ non-toxic
- ✓ less traumatic
- ✓ Hemodynamic profiles

Terminology

Device Parameters

Size	25 mm	27 mm	29 mm	31 mm	33 mm
A	25	27	29	31	31
B	28	29.5	31.5	33.5	33.5
C	36	38	40	42	44
D	7	7.5	8	8.5	8.5

A	IOD, Stent diameter
B	Tissue annulus diameter (TAD)
C	External sewing ring diameter (ESRD)
D	Anterior effective profile



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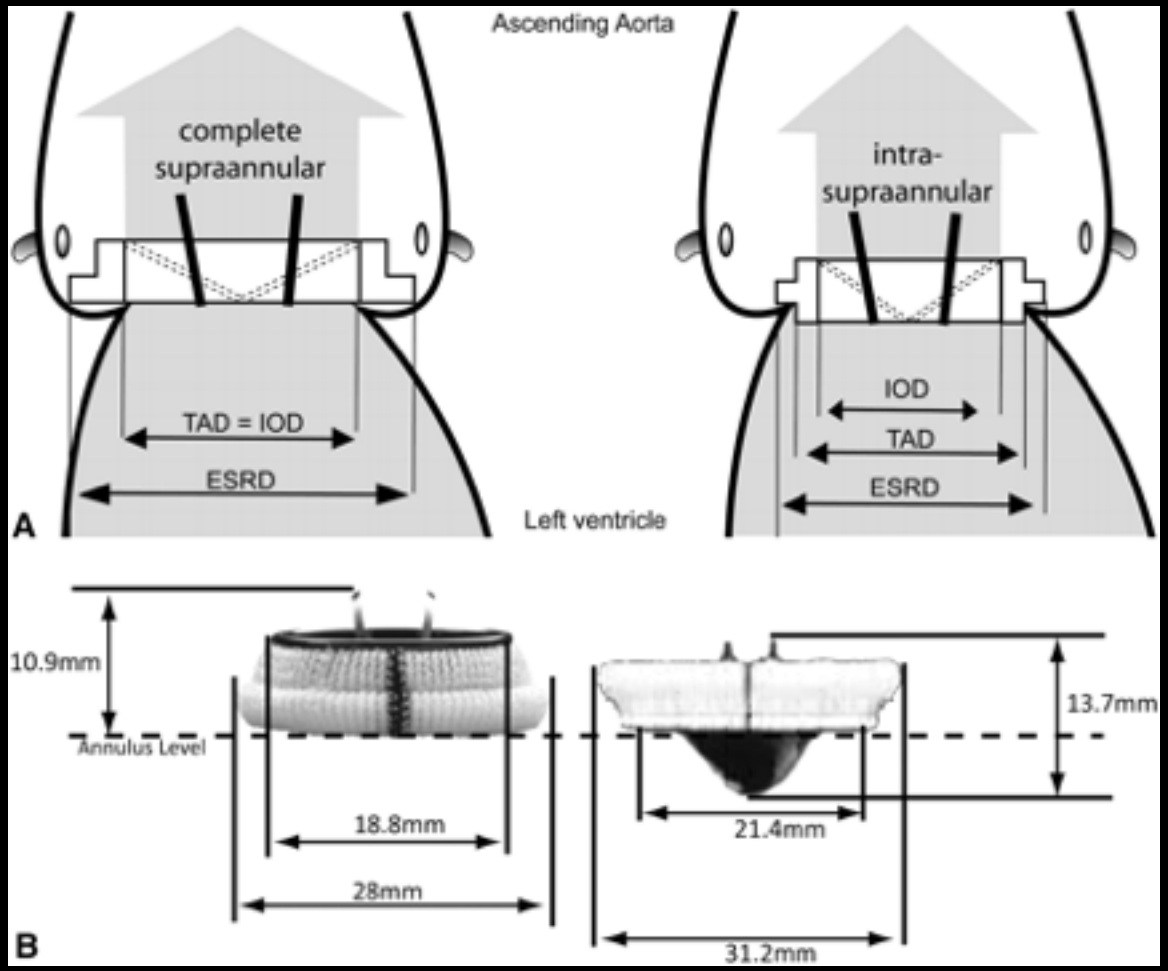
Terminology

Device Parameters



J Thorac Cardiovasc. Surg. 2008;136:462-471.

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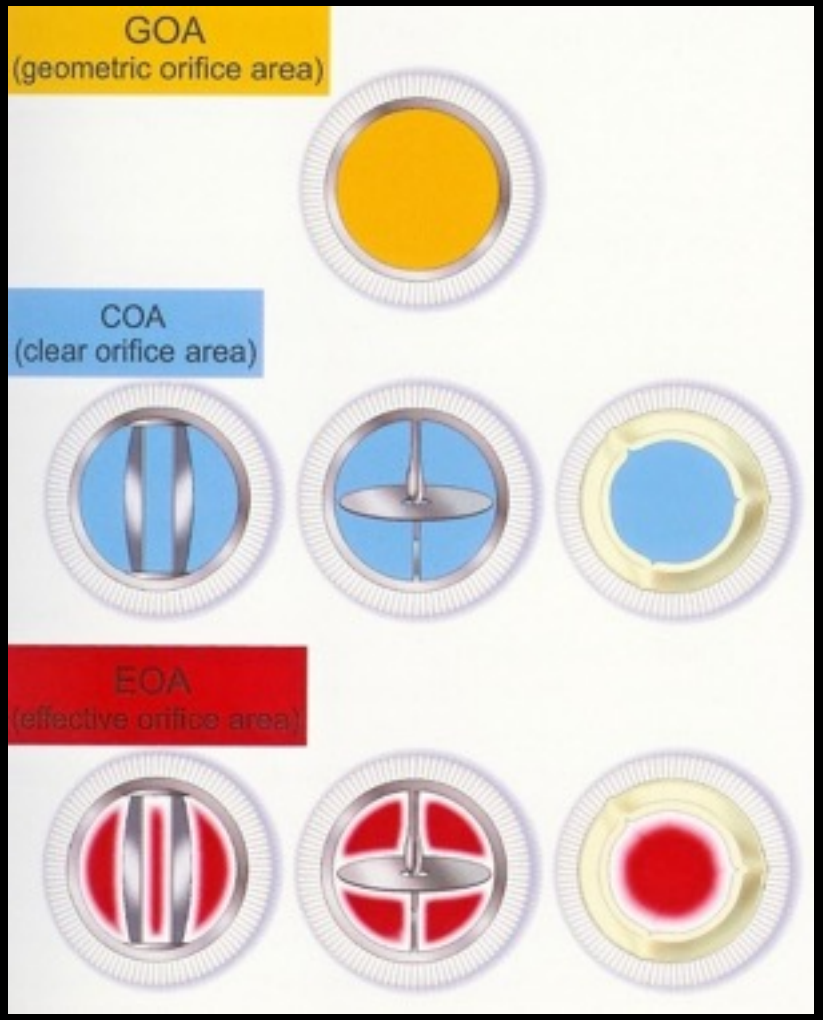
Terminology

Effective Orifice Area (EOA)

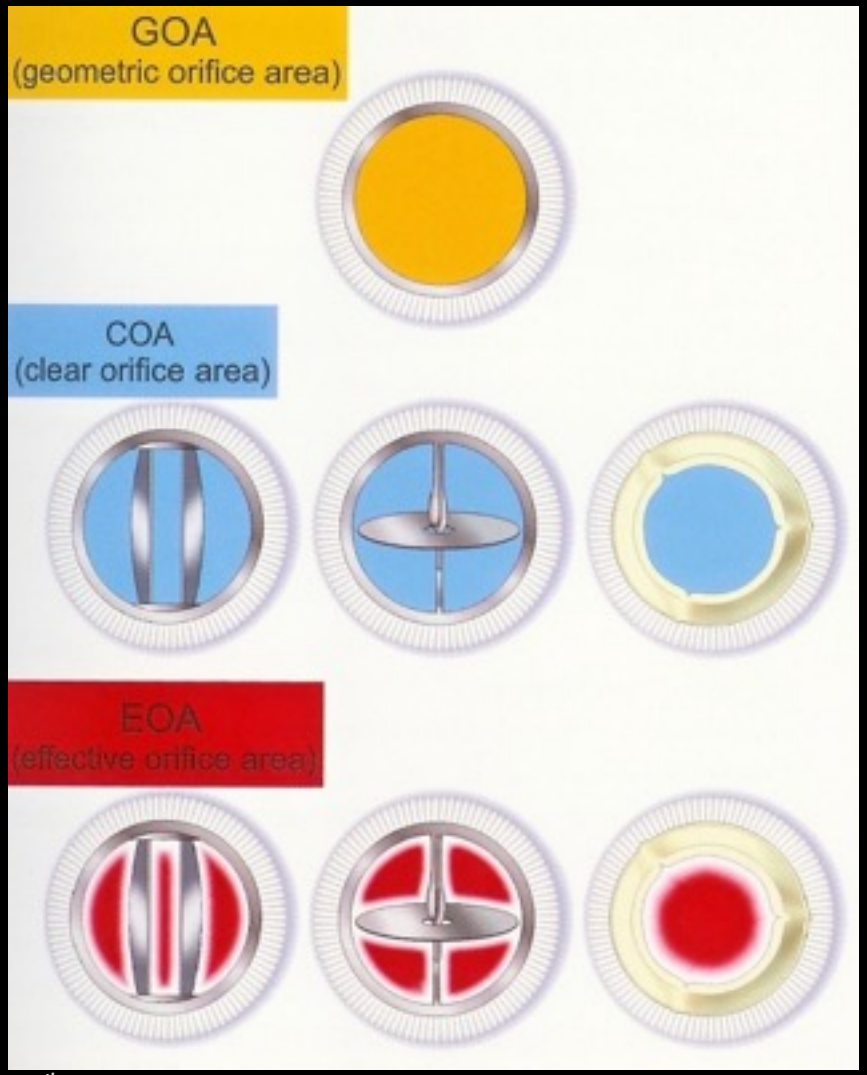
- the most important parameter.
- Both mechanical and tissue valve

- EOA, the blood really flows.
- Indexed EOA (IEOA) : EOA related to $1m^2$ of pt's BSA.



Terminology

Effective Orifice Area (EOA)



<u>For preventing PPM</u>

IEOA should be greater than

- 0.85 cm^2/m^2 in aortic position
- 1.2 cm^2/m^2 in mitral position

Various type of Artificial Heart Valve

Mechanical valve

Various type of Artificial Heart Valve

Mechanical valve (bileaflet valves)

Valve	Material	Position	Radiographic Characteristics	FDA Approval
The Medtronic-Hall® Prosthesis	Housing: Titanium Disc: Pyrolytic carbon Sewing Ring: Knitted PTFE, standard	Aortic and Mitral	Housing is radiopaque; disc is radiolucent	2002
The Sorin Allcarbon® tilting disc	Housing: Stellite 25, a chrome alloy Disc: Pyrolytic carbon over a graphite substrate Sewing Ring: Teflon	Aortic and Mitral	Disc has a tantalum wire that is radiopaque	—
ATS open pivot® bileaflet (Standard Series)	Orifice Ring: Pyrolytic carbon Leaflets: Pyrolytic carbon over graphite substrate Sewing Ring: Dacron	Aortic and Mitral	Titanium ring is radiopaque; leaflets are visible due to high tungsten content	2000
Edwards Mira® Valve	Orifice Ring: Pyrolytic carbon Leaflets: Pyrolytic carbon over graphite substrate Sewing Ring: Dacron	Aortic and Mitral	Titanium ring is completely radiopaque; leaflets impregnated with tungsten	—
The MCRI On-X	Orifice Ring: On-X carbon Leaflets: On-X carbon over graphite substrate Sewing Ring: PTFE	Aortic and Mitral	Leaflets impregnated with tungsten	2001 (aortic) 2002 (mitral)

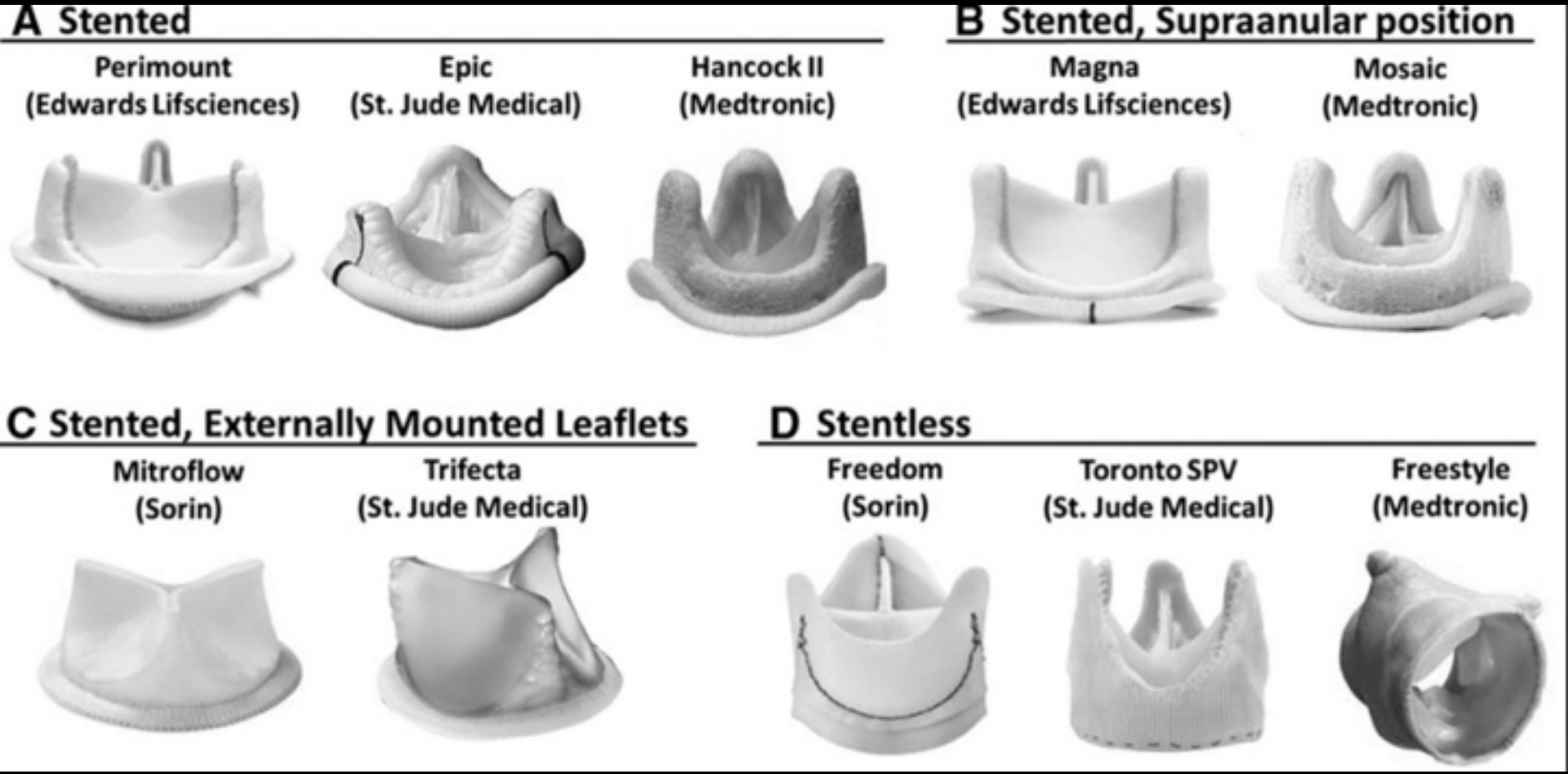
Various type of Artificial Heart Valve

Mechanical valve (bileaflet valves)

The Sorin Bicarbon® mechanical valve	Housing: Titanium Leaflets: Pyrolytic carbon Sewing Ring: PTFE	Aortic and Mitral	Leaflets and housing are radiopaque	—
The St. Jude Medical (SJM) Standard® bileaflet valve	Housing: Graphite coated with pyrolytic carbon Leaflets: Graphite coated with pyrolytic carbon Sewing Ring: Polyester, PET, or PTFE	Aortic and Mitral	Leaflets impregnated with tungsten	1977
SJM Regent® bileaflet valve	Housing: Graphite coated with pyrolytic carbon Leaflets: Graphite coated with pyrolytic carbon Sewing Ring: Polyester, PET, or PTFE	Aortic and Mitral	Leaflets impregnated with tungsten	2002
SJM Masters® with Silzone coating	Cage Material: Pyrolytic carbon over graphite substrate Leaflets: Pyrolytic carbon with graphite substrate Sewing Ring: PET polyester	Aortic and Mitral	Leaflets impregnated with tungsten	Withdrawn January 2000
Standard Sulzer® Carbomedics Valve	Housing: Pyrolytic carbon Leaflets: Pyrolytic carbon-coated Sewing Ring: Dacron	Aortic and Mitral	The titanium ring surrounding the housing and leaflets is radiopaque	1993

Various type of Artificial Heart Valve

Tissue Valve



Ulbercht JS et al. Clin Infect Dis. 2004(39);S73-82

Various type of Artificial Heart Valve

Tissue Valve

Valve	Tissue	Material	Location	Radiographic Characteristics	FDA Approval
CE porcine®	Porcine	Sewing ring: molded silicone rubber covered by PTFE cloth Stent material: PTFE cloth Stent: Elgiloy	Aortic or Mitral	Elgiloy® stent is radiopaque	1976
CE SAV®	Porcine	Sewing ring: molded silicone rubber covered by PTFE cloth Stent material: PTFE cloth Stent: Elgiloy	Aortic	Elgiloy® stent is radiopaque	2002
Hancock MO® stented	Porcine	Sewing ring: Dacron Stent: polypropylene	Aortic	Haynes® alloy ring at the annulus	1978
Hancock II® stented porcine	Porcine	Porcine valve Stent: acetyl homopolymer	Aortic, Mitral	Haynes® alloy, scalloped stent, metal ring and eyelets	1999
CE PERIMOUNT®	Bovine Pericardium	Sewing ring: silicone rubber with nonwoven polyester Stent material: woven polyester Stent: Elgiloy	Aortic or Mitral	Elgiloy® stent is radiopaque	1991 (aortic) 2000 (mitral)
Freestyle®	Porcine	Polyester cloth covering a porcine valve	Aortic	—	1997
T-SPV®	Porcine	Polyester cloth covering a porcine valve	Aortic	—-	1997
St. Jude Medical Biocor®	Porcine	Sewing ring: Dacron Stent material: polyester Stent: acetal copolymer	Aortic and Mitral	Contains wire in sewing ring	2005

Mechanical vs. Biological

Major Problems

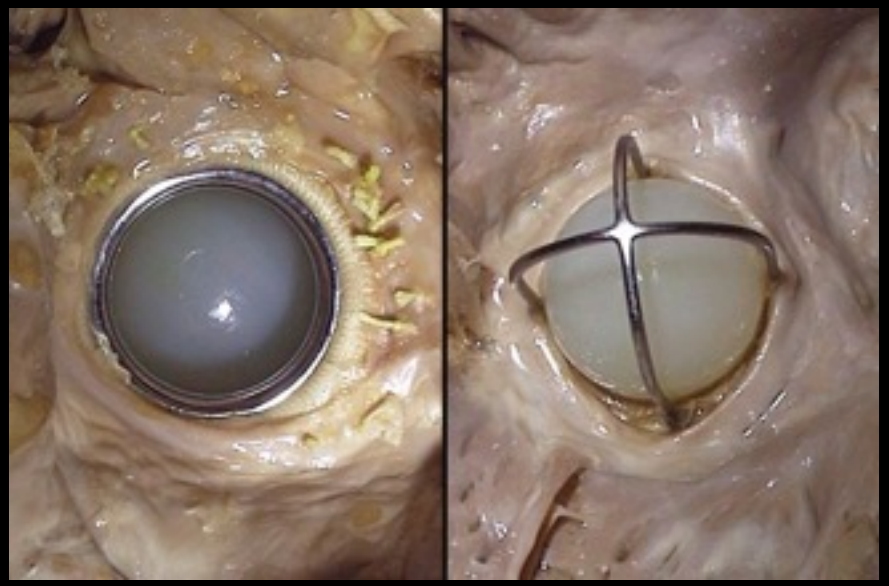
Mechanical valve	Biological valve
Thrombosis	SVD (Calcification, Cusp tear)
pannus formation	Dehiscence
paravalvular leak	infection
infection	pannus
bleeding	paravalvular leak

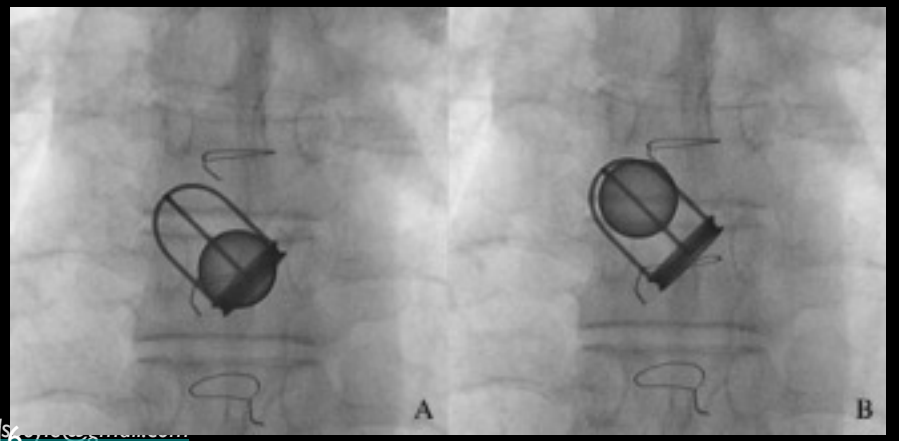
Mechanical Heart Valve

Caged Ball valve

- 1960, first clinical use in mitral replacement.

- No central blood flow
- Increased work-load
- Blood cell damage
- Thromboembolism





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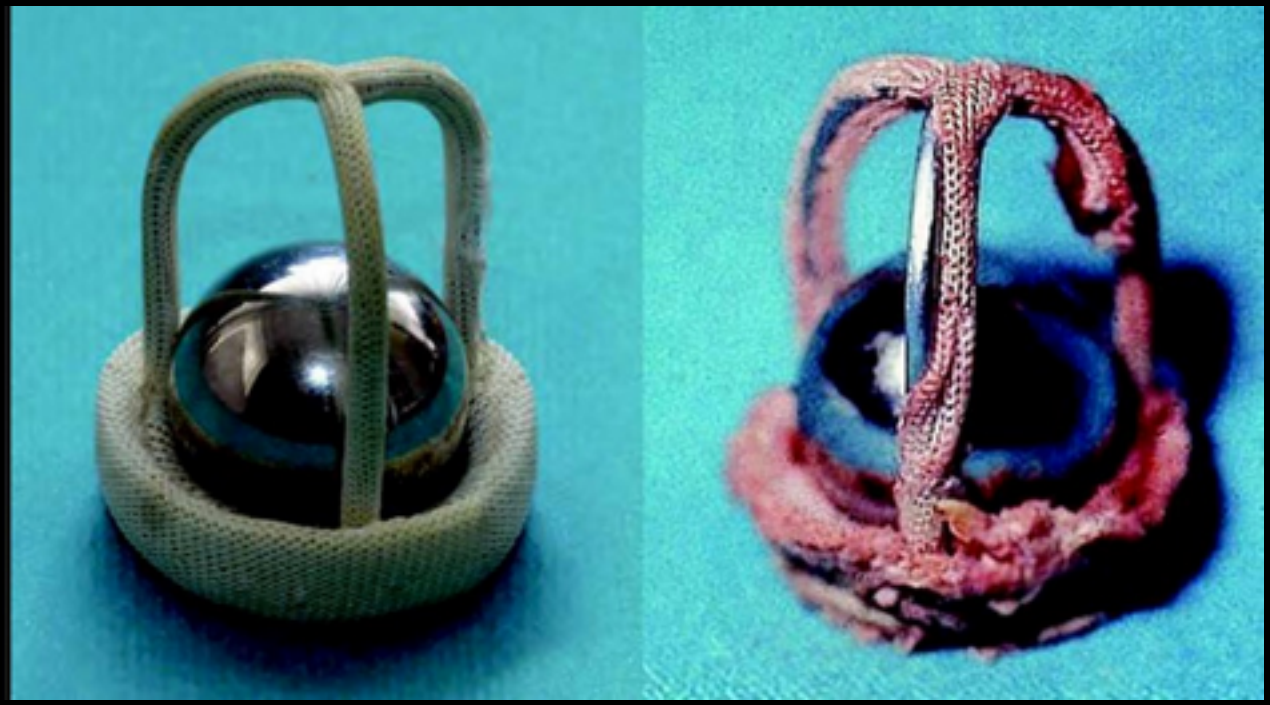
Mechanical Heart Valve

Caged Ball valve

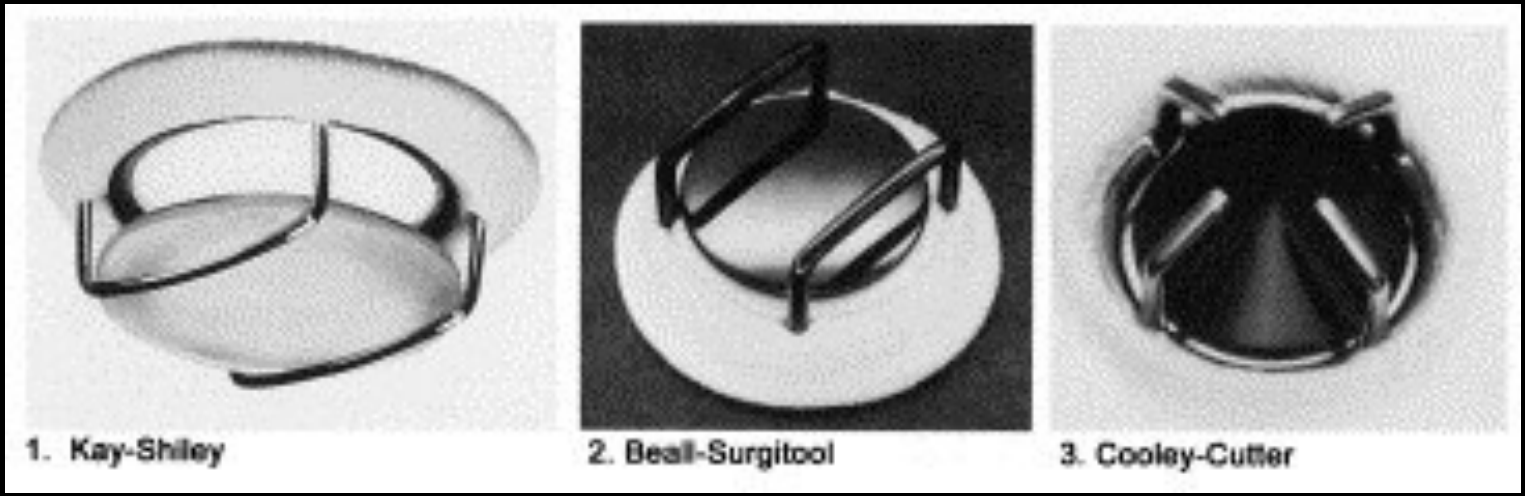
- Cloth-covered developed, but tearing occurred



Mechanical Heart Valve

Non-Tilting Disc valve

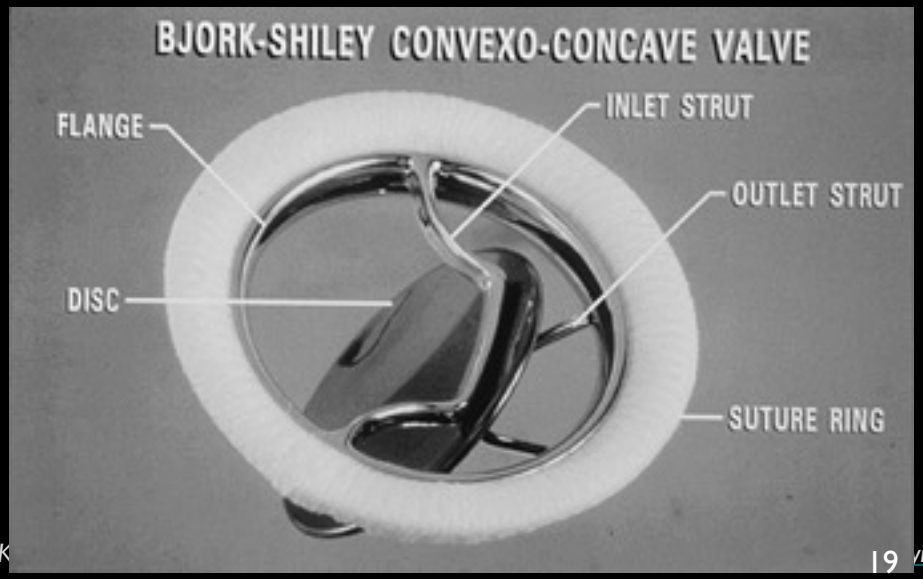
- Low profile design, easy implantation, little opening resistance, short closure delay time (low AR or MR).
- But, higher flow gradient, significant turbulence, hemolysis, thromboembolic complications.



Mechanical Heart Valve

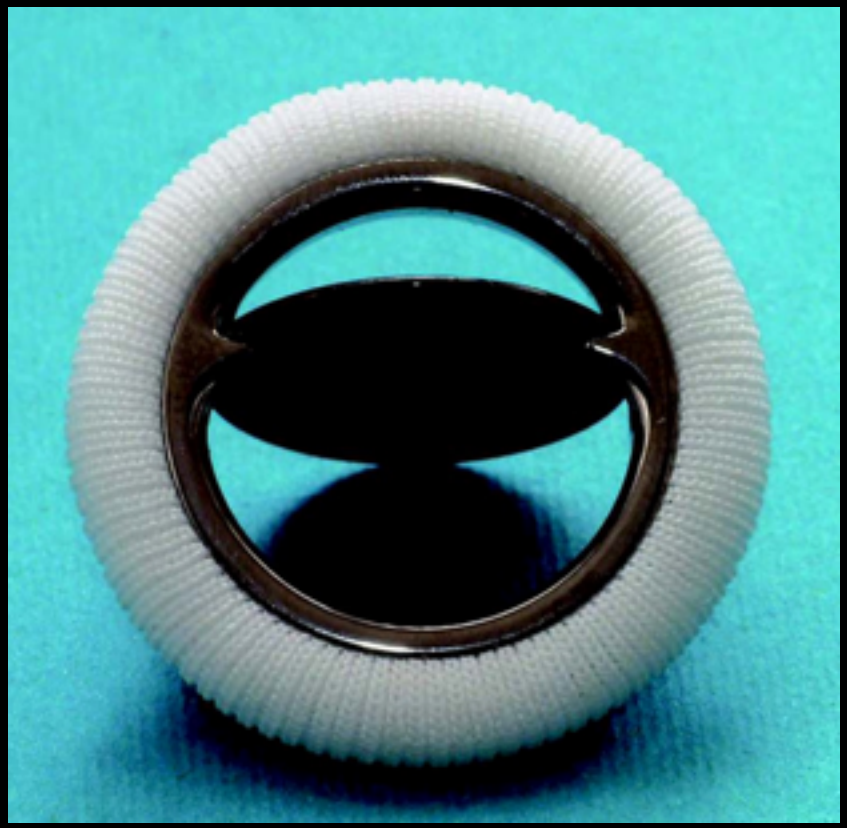
Tilting mono Disc valve (Bjork-Shiley)

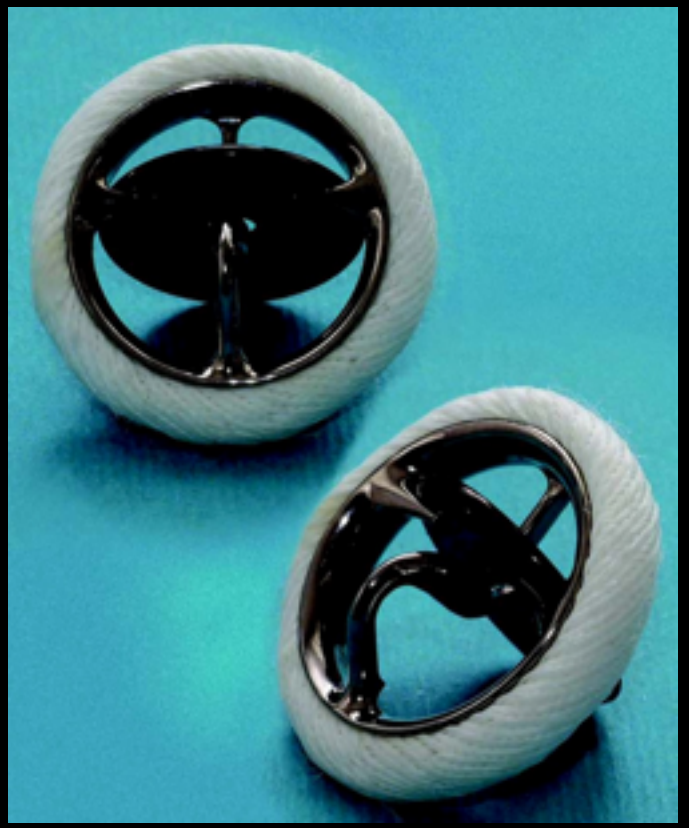
- First model in 1969, most-often implanted valves in the 1970s and 1980s
- Carbon flat disc tilting up to 60°-70°
- Standart type → convex concave type → monostrut type
- But, inflow bar broken and disc escape !! (2% / year)



Mechanical Heart Valve

Tilting mono Disc valve (Omniscience, Medtronic Hall)





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Mechanical Heart Valve

Bileaflet Valves : SJM (1977)

- Different tilting angle, pivot design, sewing ring design.
- Open up to 85°, close at 30°

- SJM HP (1992) and SJM Regent (1998) : reduced sewing ring and enlarged EOA.

standard SJM 21mm	EOA 1.51cm^2
SJM HP	EOA 2.03cm^2
SJM Regent	EOA 2.47cm^2

** Regent 19mm EOA 1.51
(sufficient to prevent significant PPM with BSA of 2m^2)

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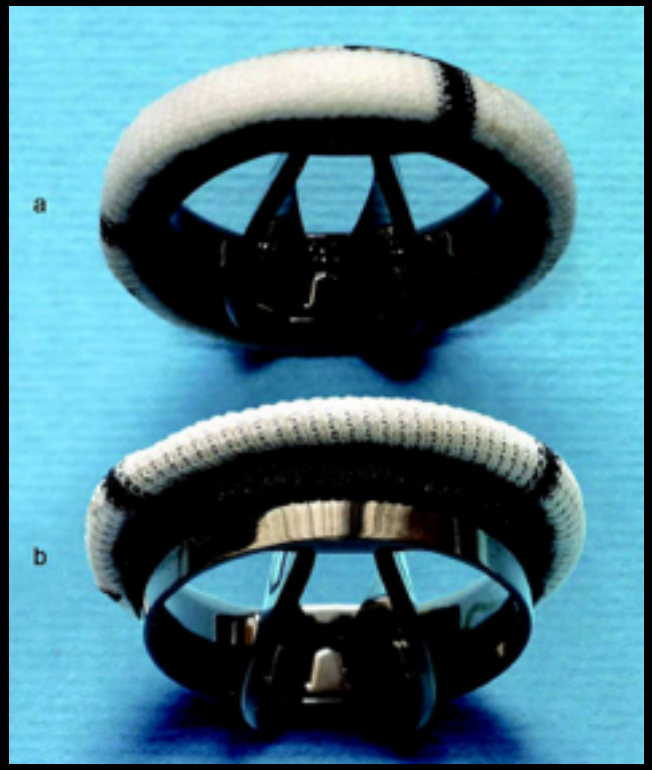
Mechanical Heart Valve

Bileaflet Valves : Bicarbon-Sorin (1990)

- Second most commonly implanted bileaflet valve
- Convex–concave shaped leaflet and tilt up to 80° and close at 20°

- a : Fitline or Slimline (suitable for small annuli)
- b: Overline (for supraannular implant)
- The same mechanism, but a different sewing cuff material, is typical for the Edwards MIRA valve (since 1997)



Mechanical Heart Valve

Bileaflet Valves : Carbomedics (1986)

- Standard : leaflets tilt up to 78° and close at 25°, tilting range of 53°
- R : response to the problem of a small aortic annulus
- Top Hat : Totally supra annular implantation

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Mechanical Heart Valve

Bileaflet Valves : Carbomedics (1986)

- Orbis : Universal Aortic and Mitral Valve: Enabling implantation of the same valve either to the aortic or mitral position

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Mechanical Heart Valve

Bileaflet Valves : ATS (1992)

- Standard Type and AP type (Advanced Performance) for small Annuli

Case

	Edward Magna	Trifecta	
Leaflet	Bovine Pericaridum		
sewing ring	Silicon rubber	Silicon rubber	
Stent	Cobalt-chronmium	Titanium	
Fabric ecovoering stent	polyester cloth	polyester cloth	

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Biological Heart Valve

General

- xenografts that are mounted on a cloth-covered stent, which is manufactured from stellite, titanium, or plastic.
- Slight flexibility, helps to absorb stress load and thereby prolong the durability.
- The stent is covered with Teflon or polypropylene.
- Either a porcine aortic valve or a valve assembled from bovine pericardium.
- detoxification (anticalcification, antidegenerative, antimineralization) treatment incorporated into the processing and storage of tissue valves

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Biological Heart Valve

Porcine valve

- St Jude Epic®, Hancock II®, Medtronic-Mosaic®

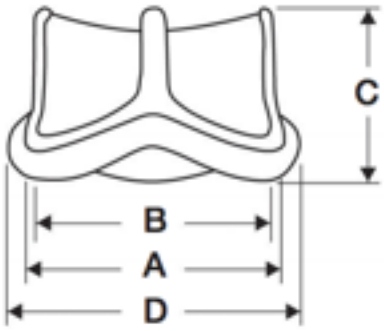
Biological Heart Valve

Bovine Pericardial valve

- Sorin Soprano®, C-E Perimount Magna®
- St Jude Trifecta®, Sorin Mitroflow®

Edward Magna®

Specifications



Model 3000/ 3000TFX

Size	19 mm	21 mm	23 mm	25 mm	27 mm	29 mm
A. Stent Diameter (TAD)	19	21	23	25	27	29
B. Internal Diameter (Stent I.D.)	18	20	22	24	26	28
C. Profile Height	14	15	16	17	18	19
D. External Sewing Ring Diameter	24	26	28	30	32	34

Significant dimensions in millimeters (nominal values)

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St Jude Epic Supra®

Epic™ Supra Stented Tissue Valve with Linx™ AC Technology

Ordering Information View Catalog

Contents: Aortic Supra-Annular Stented Tissue Valve (1 unit per box)

Reorder Number	Valve Size (mm)	Tissue Annulus Diameter (mm)	Internal Diameter (mm)	Aortic Protrusion (mm)	Total Height (mm)
ESP100-19	19	19	19	11	14
ESP100-21	21	21	21	11	15
ESP100-23	23	23	23	13	16
ESP100-25	25	25	25	13	17
ESP100-27	27	27	27	14	19
ESP100-29	29	29	29	15	20

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Trifecta®

19 mm Valves

Figure 1. Mean Pressure Gradient (mmHg)

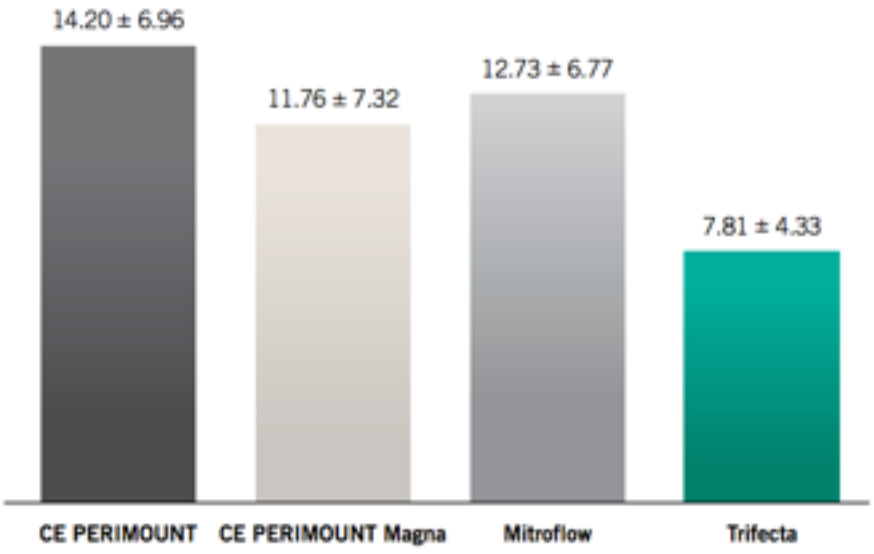
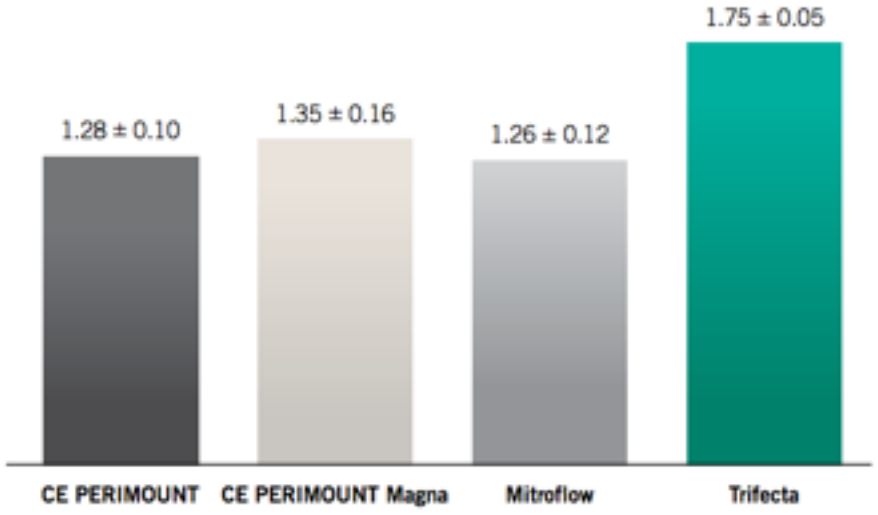


Figure 4. Effective Orifice Area (cm^2)



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Trifecta®

25 mm Valves

Figure 2. Mean Pressure Gradient (mmHg)

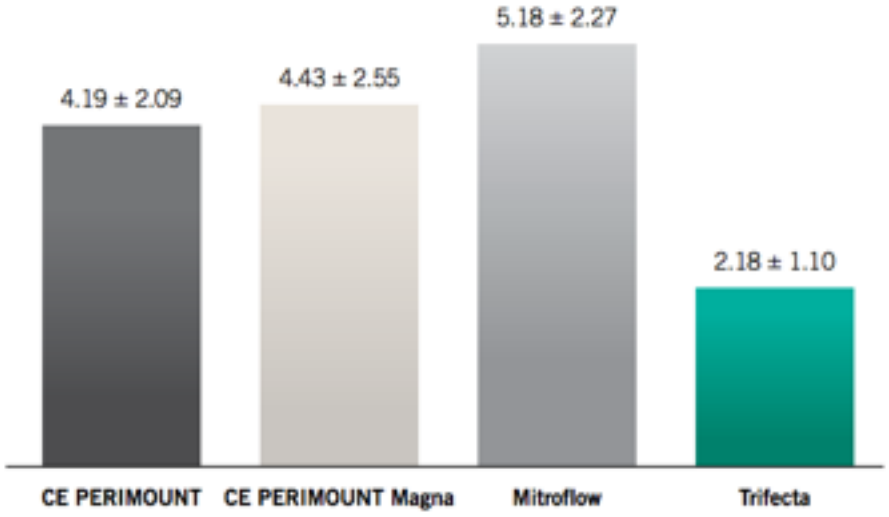
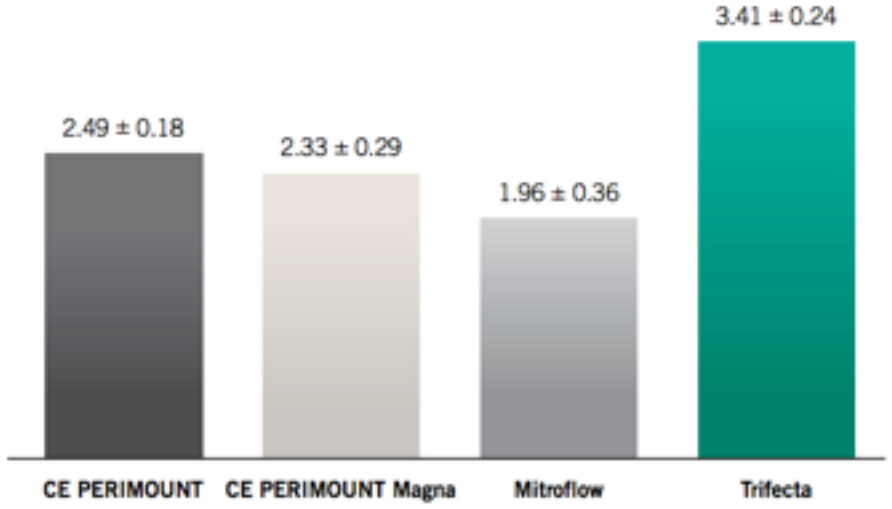


Figure 5. Effective Orifice Area (cm^2)



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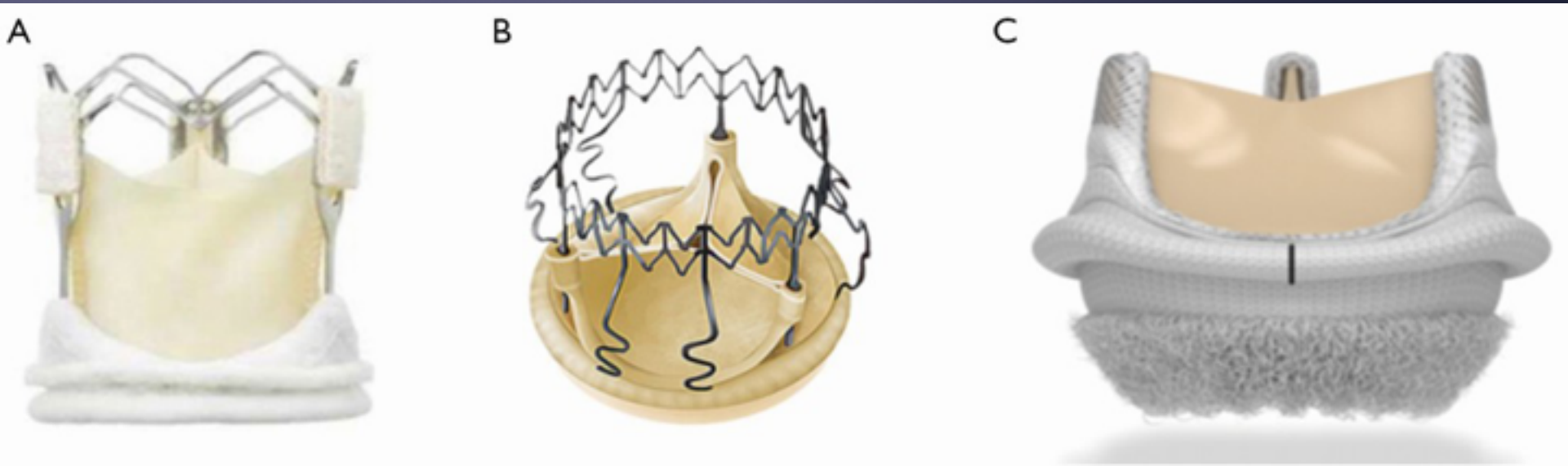
Biological Heart Valve

Sutureless valve

- Medtronic 3F Enable®, Sorin Percival®, Edward Intuity®



Biological Heart Valve

Medtronic 3F Enable®

- CE approved in 2010
- Nitinol stent.
- Equine pericardial valve leaflets
- fixed with glutaraldehyde, incorporated within a self-expanding Nitinol frame.
- without needing the placement and tying of sutures.

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Biological Heart Valve

Sorin Percival®

- CE approved in 2011
- bovine pericardium incorporated in a nitinol-cage
- The metal-cage : anchoring the prosthesis to the aortic root.

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Biological Heart Valve

Edward Intuity®

- CE approved in 2012, based on the PERIMOUNT valve
- balloon expandable stainless steel cloth-covered frame
- implanted with the aid of a delivery system.
- reduces the number of sutures required to secure the valve.

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Biological Heart Valve

Stentless valve

- Toronto SPV, 1988 by T. David, Edward prima, shelhigh superstentles, Medtronic Freestyle, Sorin Freedom
- Neither stent nor sewing ring,
- larger EOA and lower transvalvular pressure gradient.
- But, superiority in long-term data ? (vs. supraannular)
- More technical demanding and time-consuming.

Choice of Artificial Valve

Age

- Tissue valve should be preferred over 70 years in aortic and mitral position.

- But reoperation really risky ???
- Or, life expectancy would be longer than present ???

Choice of Artificial Valve

Anticoagulation therapy

- Contra-indication for anticoagulation ?
  alcoholism, under-developing country, intolerance…

Choice of Artificial Valve

Annular size and Quality

- For heavily calcified, rigid, rough annulus it is advantageous to choose the valve with wide and soft sewing ring.

- Damaged annulus such as endocarditis, allograft or stentless biopresthesis are preferred.

- Small annulus 19mm tissue valve vs. mechanical valve

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Choice of Artificial Valve

Thromboembolic risk

- Risk factors : A fib. Large LA size (>55mm), Hx of embolism
- Should be given a mechanical valve.

Choice of Artificial Valve

Pregnancy

- If aortic position, Ross operation is preferred (?).
- Warfarinization during first trimester, 5-10% risk rate of fetal anomaly.

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Choice of Artificial Valve

Others

- ESRD : Mechanical ?
- Valve position : Tricuspid vs. Mitral vs. Aortic

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