

Percutaneous Pulmonary Valves: The Nevada Experience

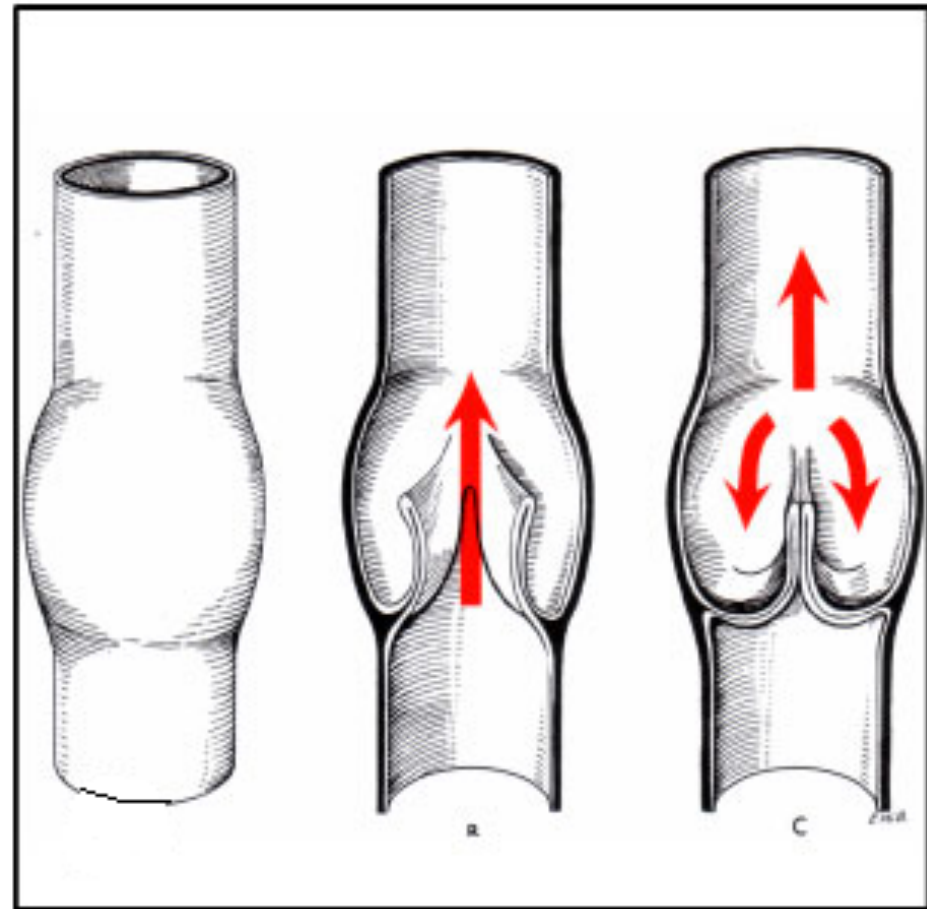
Dr. Galindo

Dr. Rothman

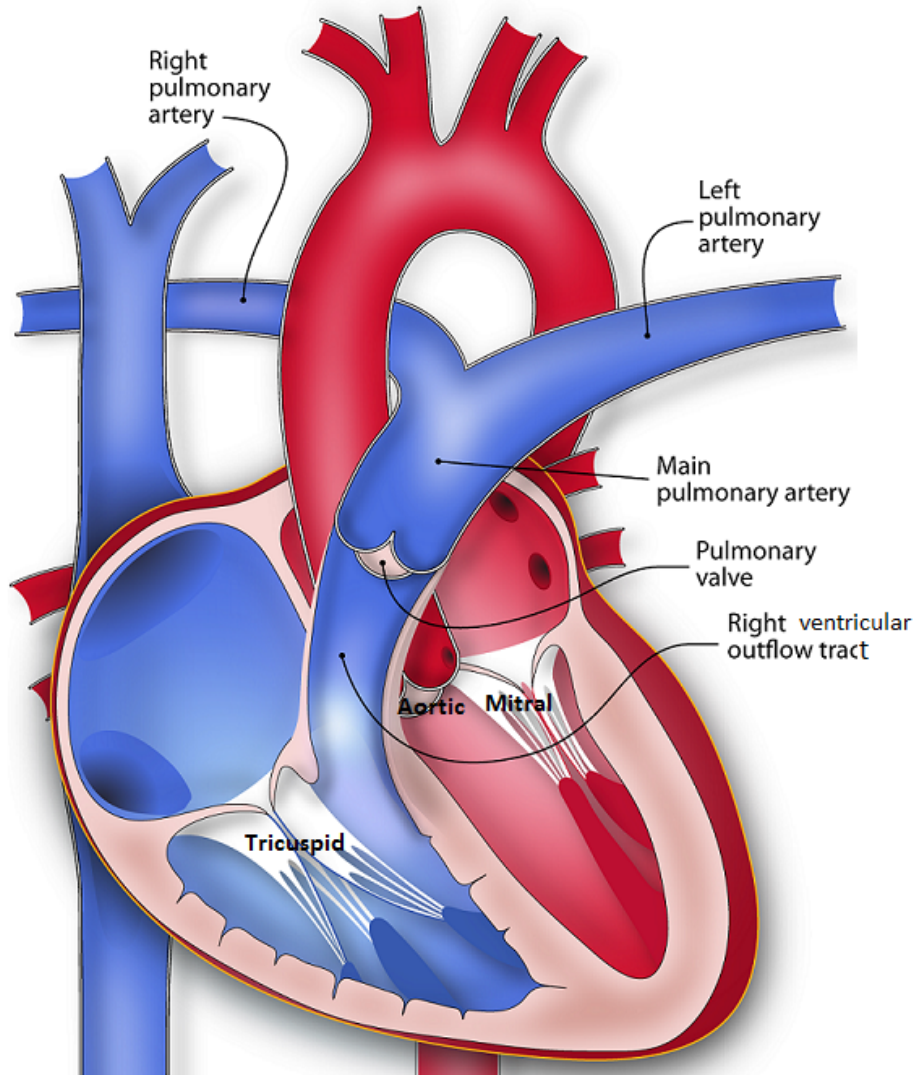


Valve Function

- Allow flow in only one direction:
 - Open to allow flow without obstruction
 - Close to keep flow from going backwards



Cardiac Valves



- Atrioventricular Valves

Tricuspid

Mitral

- Semilunar Valves

Pulmonary

Aortic

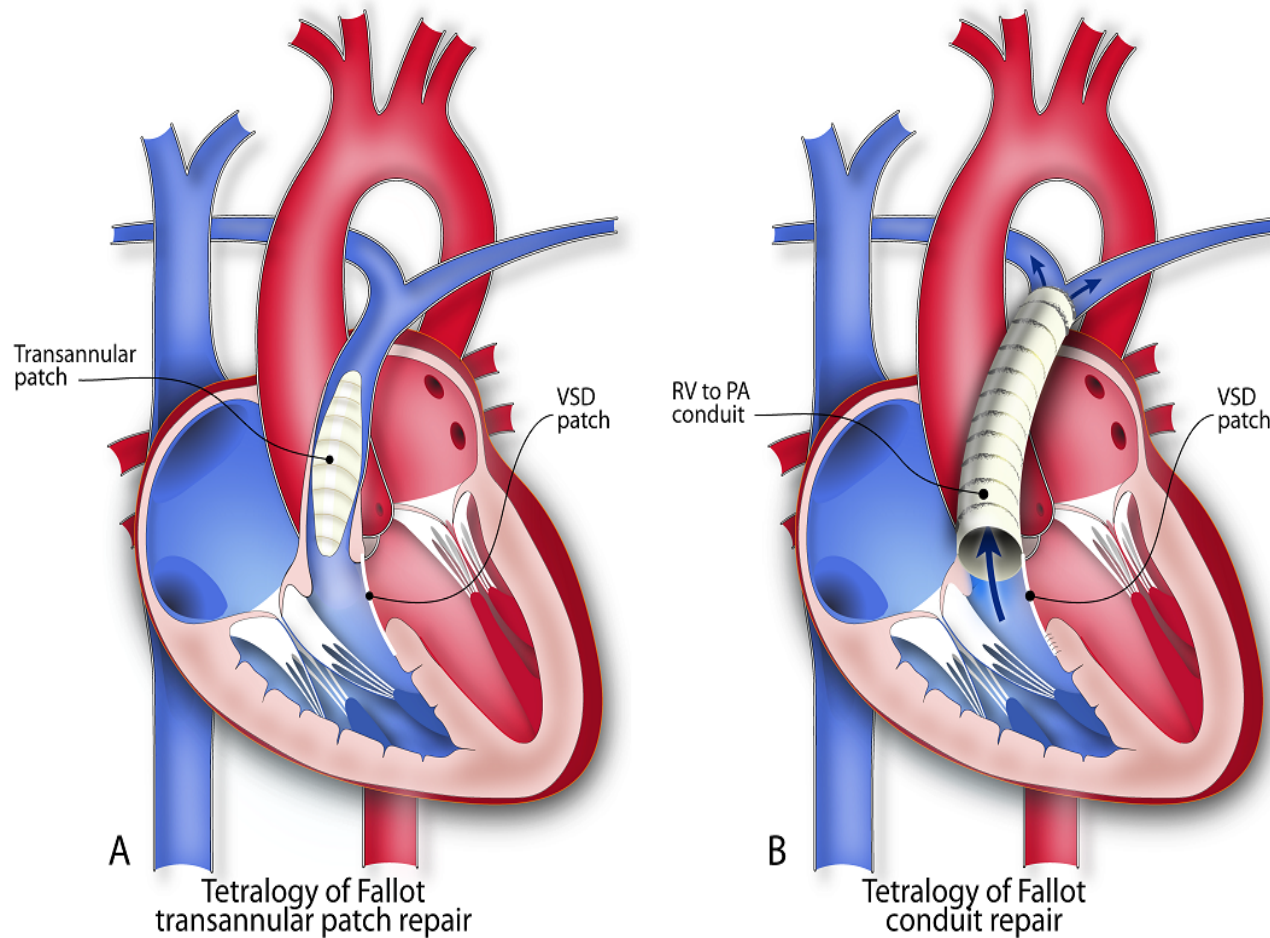
Indications for Pulmonary Valve Replacement: Preserve RV Function

- Stenosis (obstruction)
 - Gradient > 35 mm Hg
 - RV systolic pressures $> 75\%$ of systemic with normal PA pressures
 - RV hypertrophy
- Insufficiency
 - Moderate to severe pulmonary insufficiency
 - Dilated RV

Disease States

- Stenosis
 - Post-operative conduit stenosis
- Insufficiency
 - Post-operative conduit insufficiency
 - Post-operative Tetralogy of Fallot repair – transannular patch
 - Following pulmonary balloon valvuloplasty

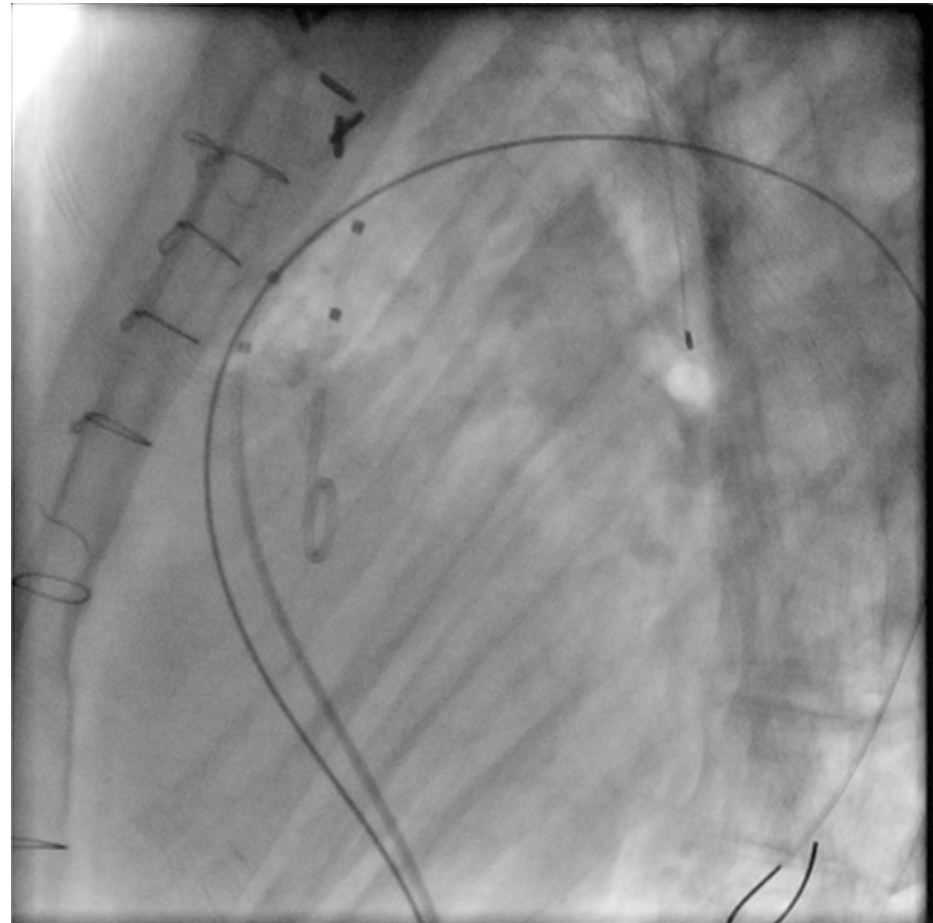
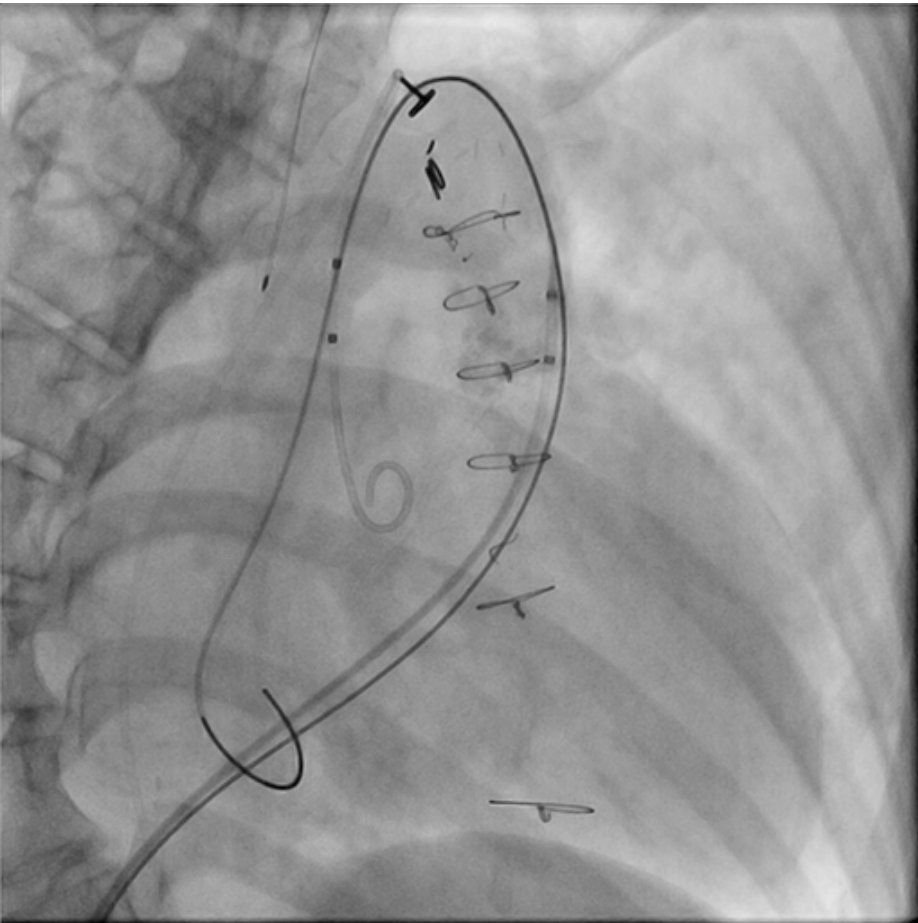
Repair of Tetralogy of Fallot: RV Outflow Tract Patch vs. Conduit



RV-PA Conduits are Used to Palliate Complex Heart Defects

- Severe Tetralogy of Fallot
- Pulmonary atresia with VSD
- Ross procedure for aortic valve disease
- Transposition of great arteries with pulmonary stenosis and VSD (Rastelli procedure)
- Truncus arteriosus
- Some forms of double-outlet right ventricle associated with pulmonary stenosis or atresia

Homograft Stenosis/Insufficiency



Management Management Options

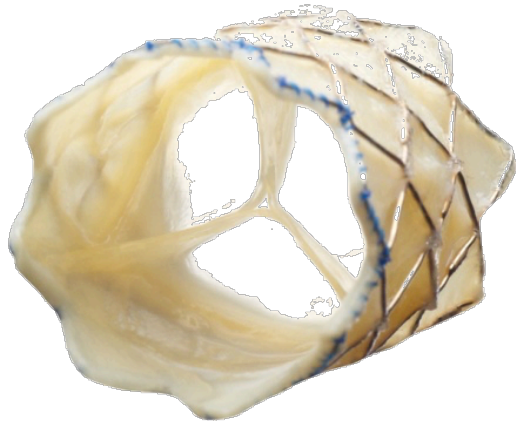
- Surgical
 - Open heart surgery to place a conduit or bioprosthetic valve between the RV and PA
- Percutaneous or transapical pulmonary valve
 - Melody Valve
 - Sapien Valve

Surgical Revision of RV-PA Homograft

- May be required every 5 – 10 years
 - Patient growth
 - Homograft stenosis/insufficiency
- Open-heart surgery on cardiopulmonary bypass
- Risk of morbidity or mortality ~ 3%
- At time of surgery there is significant risk of hemorrhage if homograft adherent to sternum

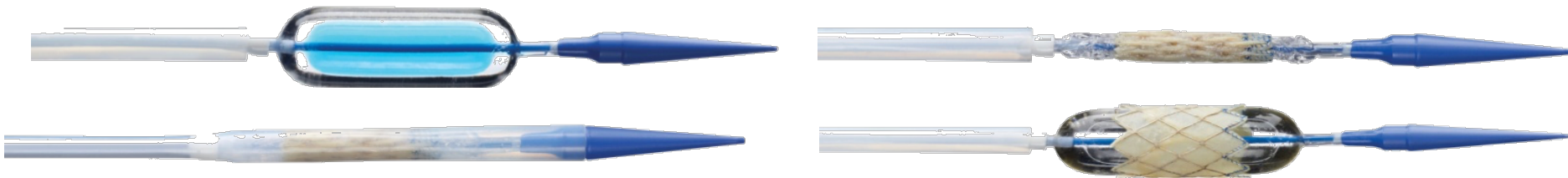
Melody[®] Transcatheter Pulmonary Valve

- 18mm Modified Contegra Bovine Jugular Vein Valve
- Sutured on a CP Platinum Iridium Frame
 - 28mm length (out of the jar)
 - Hand-crimped down to 6mm
 - Re-expanded 18mm up to 22mm



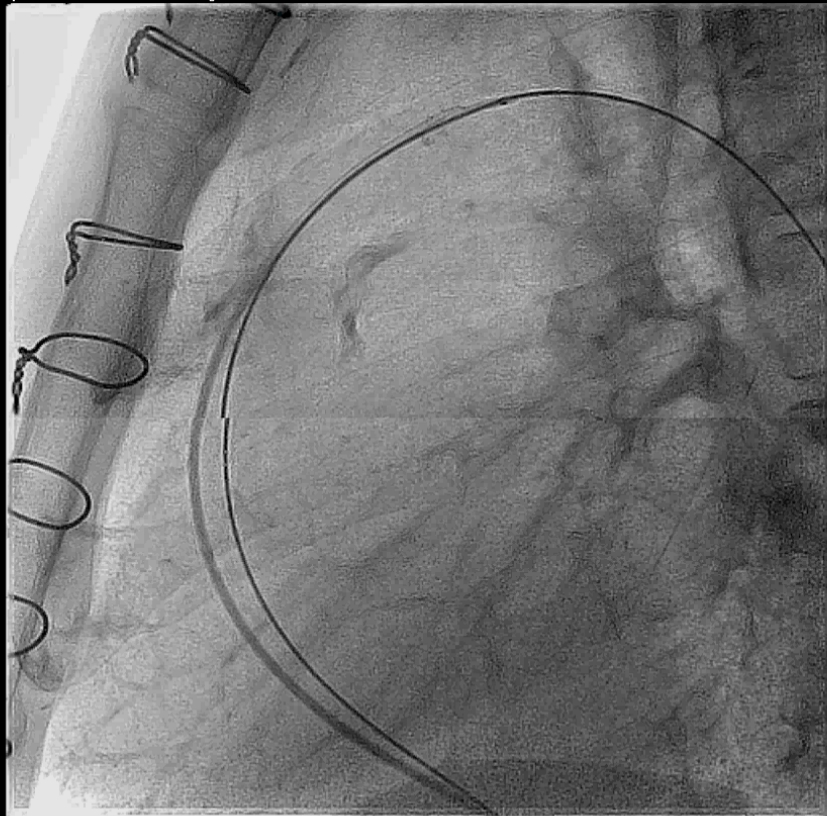
Medtronic Ensemble[®] Delivery System

- Proprietary Balloon-In-Balloon (BIB) delivery system
 - Retractable sheath covers Melody valve once it is crimped over the balloon (balloon sizes: 18, 20, 22mm)
 - 100cm length
 - 22Fr size (outer diameter)

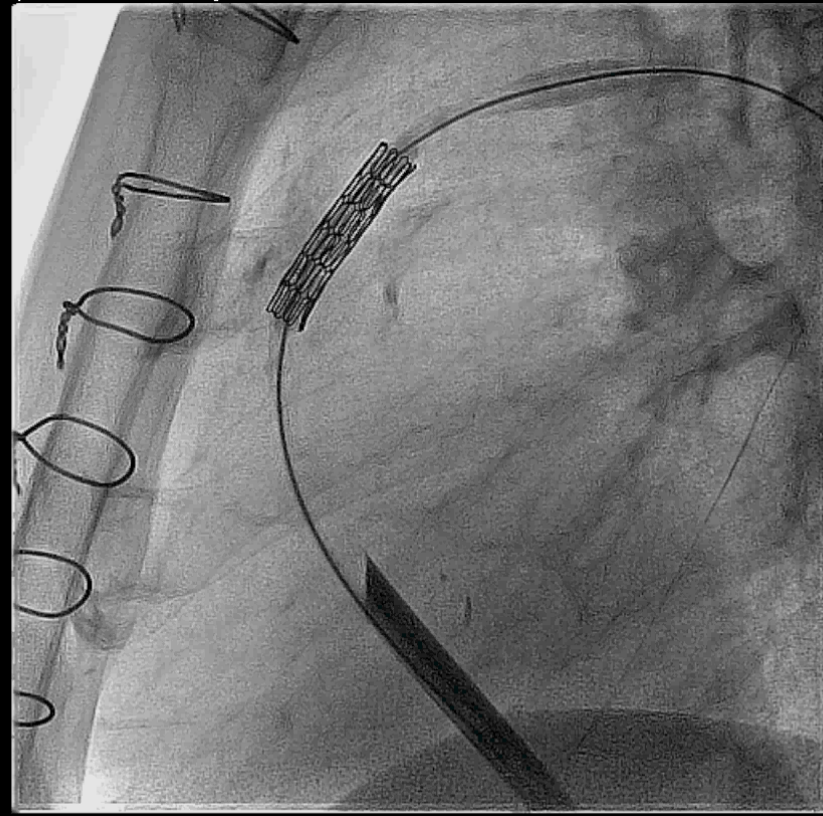


Melody Valve Deployment

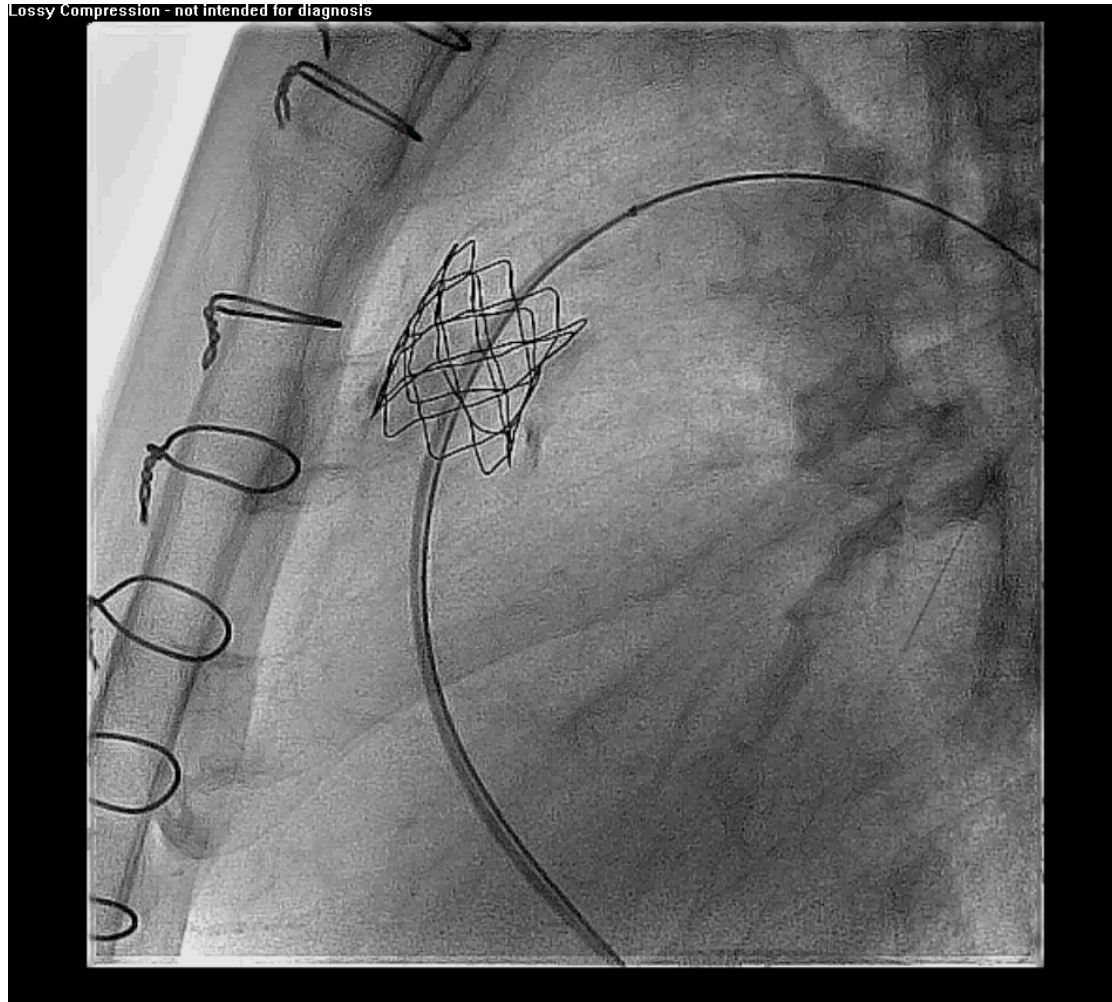
Lossy Compression - not intended for diagnosis



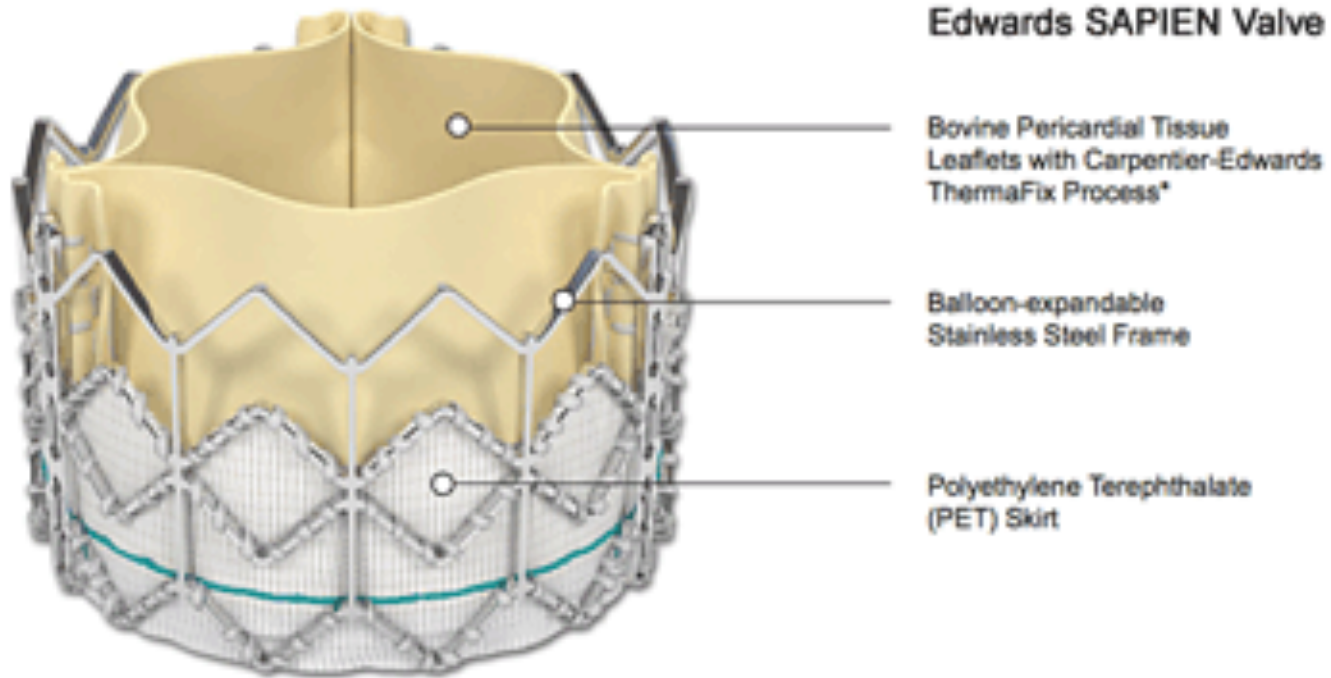
Lossy Compression - not intended for diagnosis



Melody Valve Post-Deployment



Edwards Sapien Valve



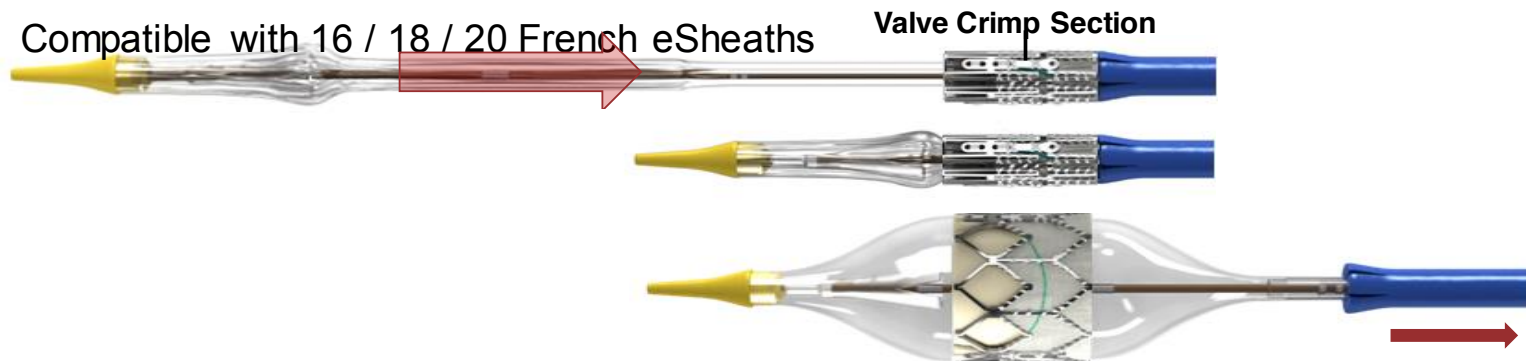
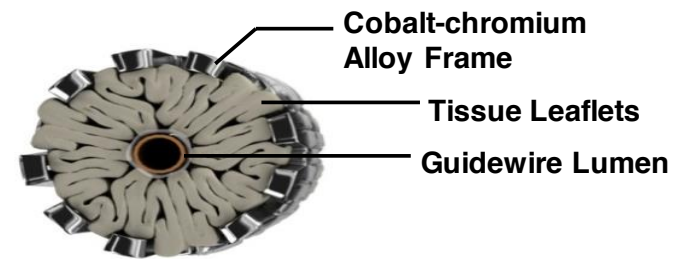
Sapien XT and NovaFlex Delivery System: Unique Aspects

Edwards Lifesciences

NovaFlex+ Delivery System

Unique Design for Low Profile Delivery

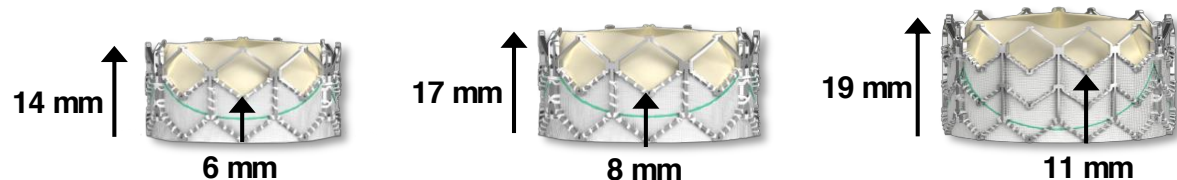
- Edwards SAPIEN XT THV is initially crimped off the balloon during preparation
- NovaFlex+ Delivery System allows the Edwards SAPIEN XT THV to be aligned onto the balloon
- Compatible with 16 / 18 / 20 French eSheaths



Valve Selection

Edwards Lifesciences

Edwards SAPIEN XT THV

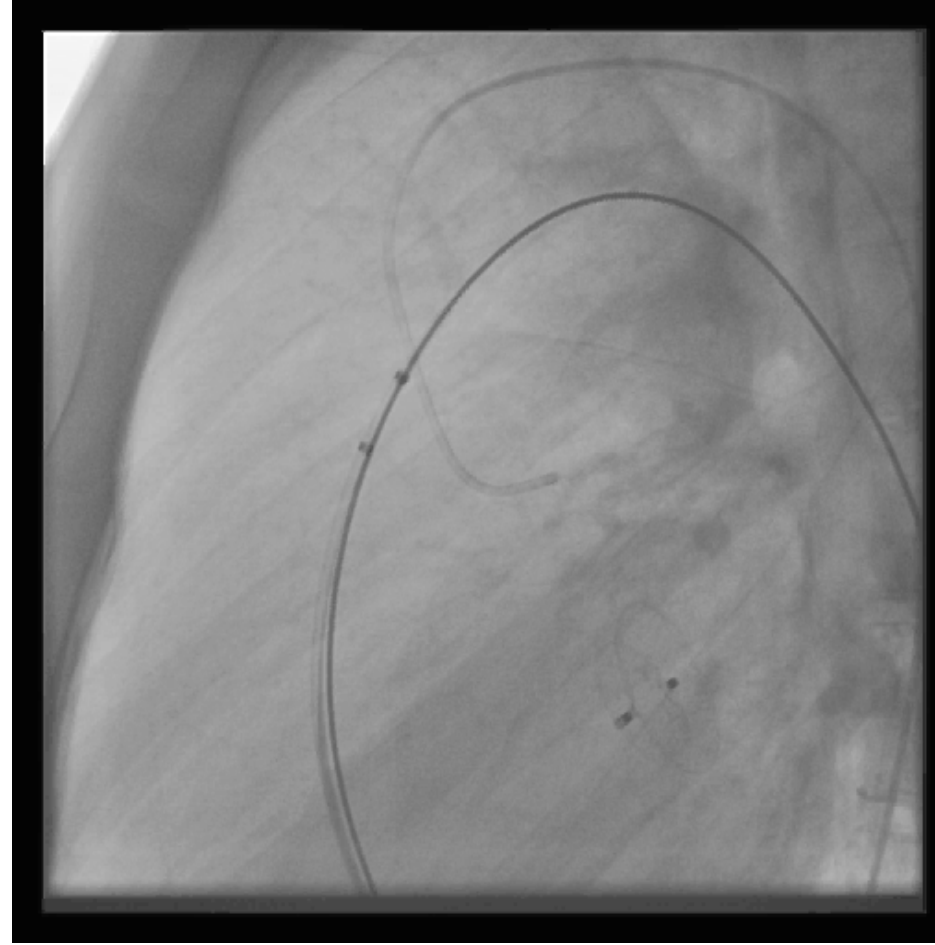


	23 mm	26 mm	29 mm
Tissue	Bovine Pericardium, Carpentier-Edwards TheraFix ¹ Anti-Calcification		
Frame	Cobalt-Chromium Alloy		
Tissue Thickness	0.3 mm - 0.4 mm	0.3 mm - 0.4 mm	0.4 mm - 0.5 mm
Pulmonic THV sizing: <i>Non-Compliant Landing Zone Diameter During Balloon Predilation</i>	20 – 23 mm	23 – 26 mm	26 – 29 mm
Crimped Height	17 mm	20 mm	22 mm
Expanded Height	14 mm	17 mm	19 mm
Foreshortening	3 mm	3 mm	3 mm
Fabric Skirt Height²	6 mm	8 mm	11 mm

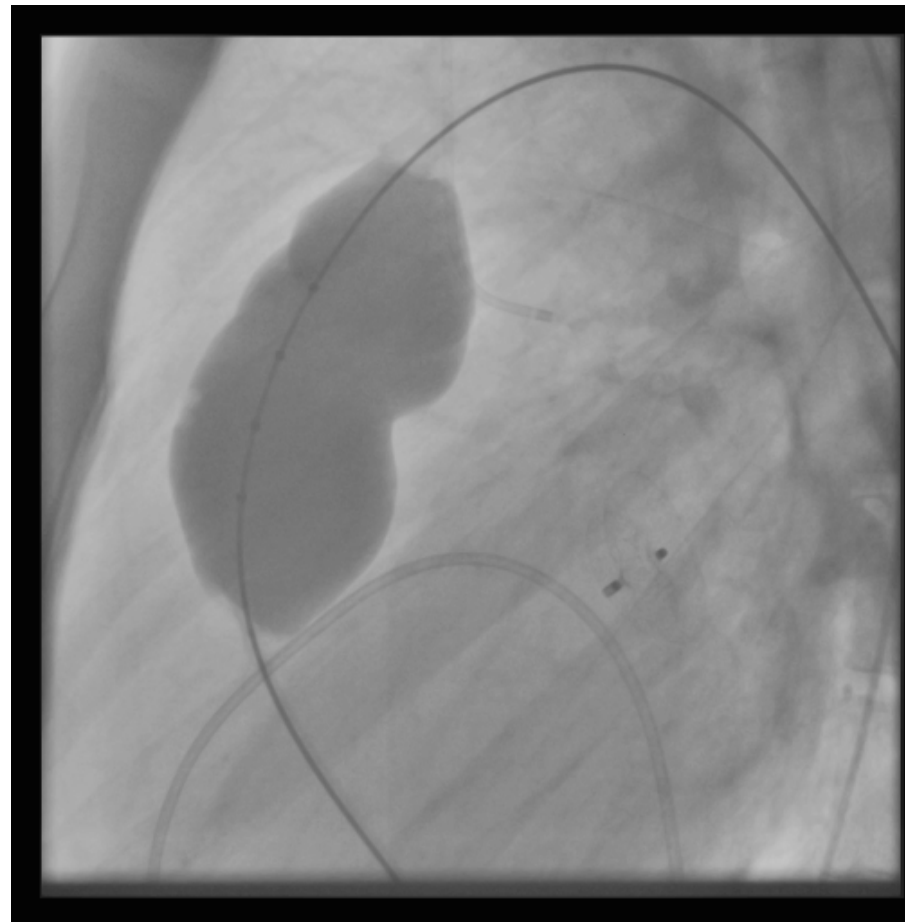
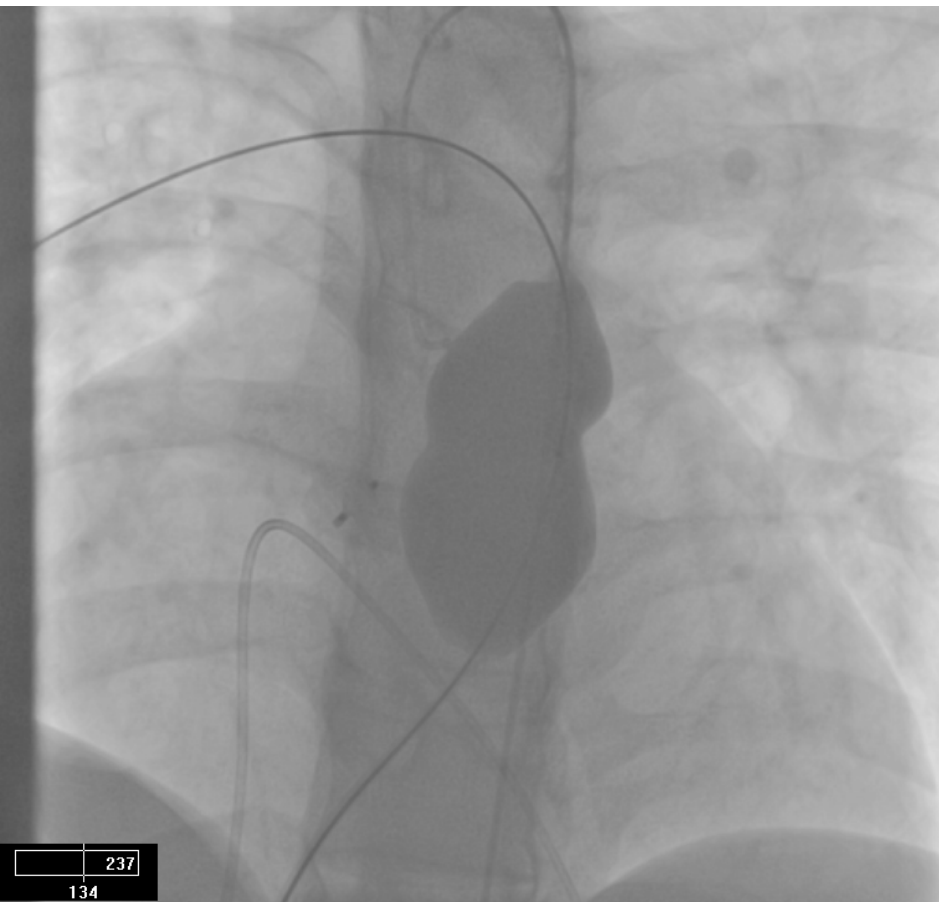
¹No clinical data is available with which to evaluate the long-term impact of the Carpentier-Edwards TheraFix tissue process in patients

²Fabric skirt height for bottom zigzag

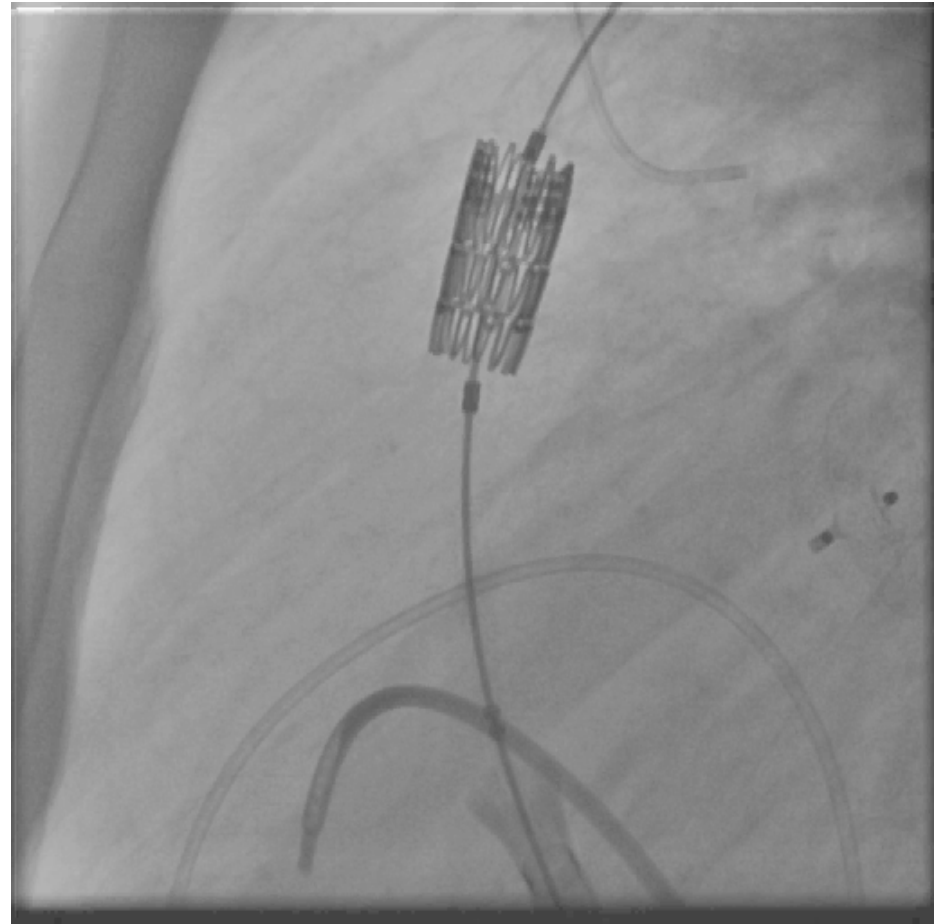
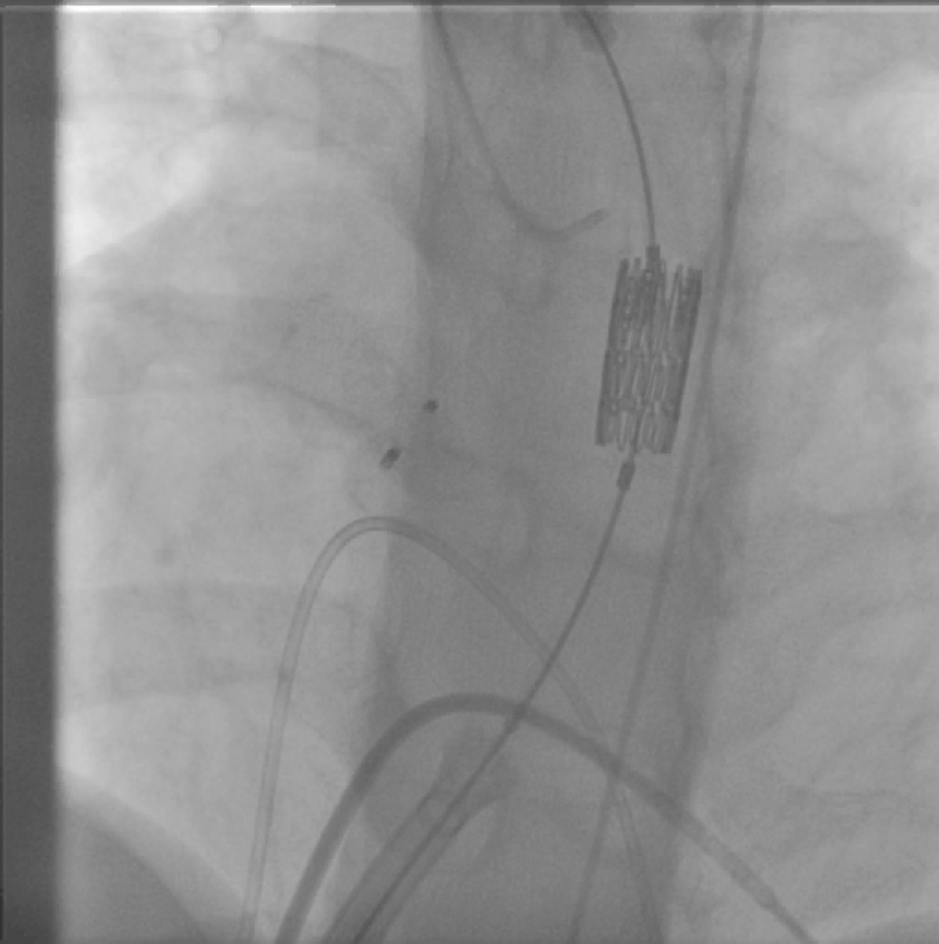
Pulmonary/Coronary Angiogram



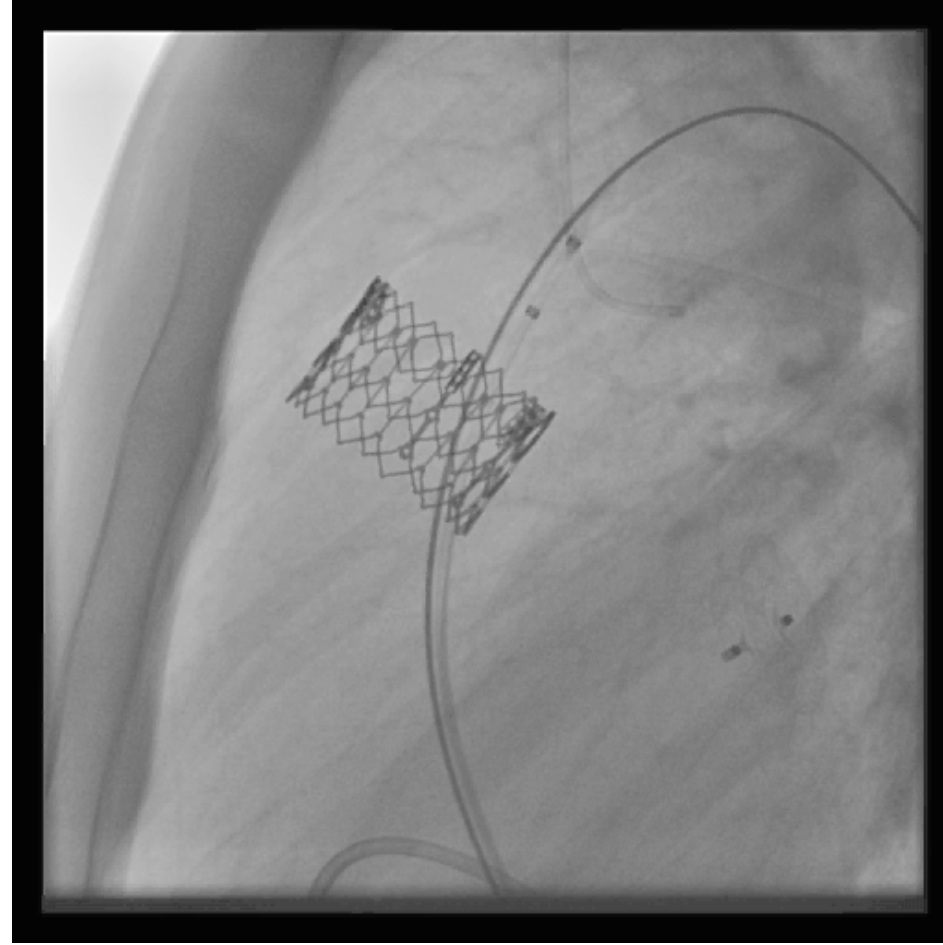
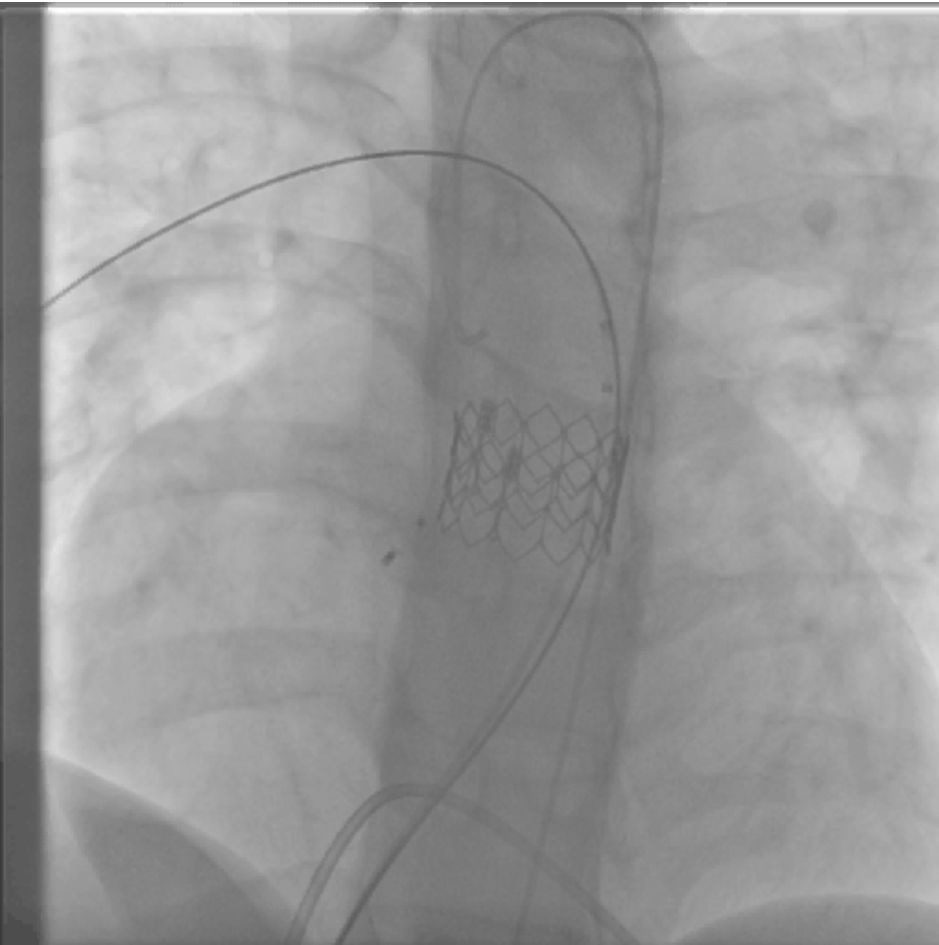
Balloon Sizing



Sapien Valve Deployment



Pulmonary Angiogram Post Sapien Valve



Nevada Experience

- Percutaneous pulmonary valve program began with the Melody Valve 10/07/10
- Sapien valve introduced 8/02/13
- Both valves in use from 8/13 to 8/15
- In last 2 years we have been using the Sapien valve exclusively

	Melody	Sapien
Years in use	4 yrs 10 mo	4 yrs 2 mo
Number of patients	36	28
Age range	4 yr 1 mo - 28 yr	4 yr 11 mo - 34 yr
Lowest weight	16 kg	17 kg

Diagnosis	Melody	Sapien
Tetralogy of Fallot (TOF)	9	11
TOF/absent pulmonary valve	3	3
PA/VSD/MAPCA's	5	3
Truncus Arteriosus	4	4
DORV or D-TGA/Rastelli	4	1
Ross	1	1

Previous Surgery	Melody	Sapien
Homograft/conduit	28	9
Transannular patch	0	9
TOF repair - other	0	3
Bioprosthetic valve	2	3
Surgical/non-surgical valvuloplasty	0	4

Indications	Melody	Sapien
PS	13	4
PR	9	17
PS/PR	10	4

Pre-valve stent	Melody	Sapien
	n=27	n=11
Bare stent	25	10
Covered stent	3	2

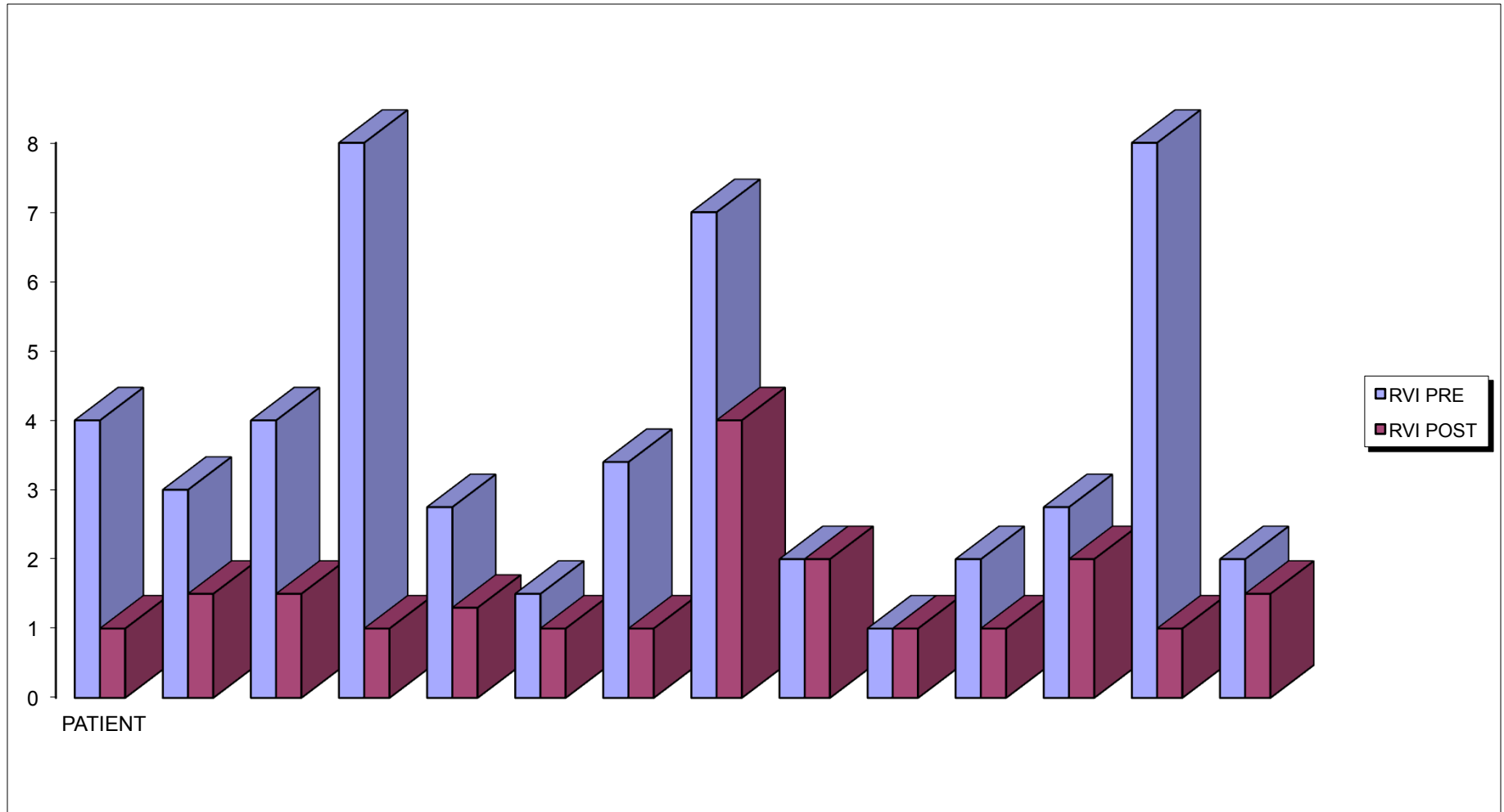
Complications	Melody	Sapien
Contained tear	7	1
Brachial plexus injury	2	0
Pulmonary hemorrhage	1	0
SVT	1	0
Ventricular ectopy	0	1
Balloon rupture	0	1
Coronary compression	0	0
Ascending aorta distortion	0	0
Endocarditis	5	0

Follow-up echocardiogram	Melody	Sapien
Stenosis (mean gradient mm Hg)		
<20	25	25
20-30	4	1
>30	1	2

Follow-up echocardiogram	Melody	Sapien
Insufficiency		
None	10	12
Mild	7	7
Mild-moderate	1	3
Moderate	1	1
Severe	0	0

Melody Valve: The Nevada Experience

Change in Right Ventricular Volume



Endocarditis

- Has only occurred with use of Melody valve
- Time from valve implant to endocarditis
 - Range from 17 months to 76 months
 - Average time frame 44.2 months
- Bacteria:
 - Enterococcus faecalis
 - Staphylococcus aureus
 - Streptococcus (gamella sanguis)
 - Streptococcus viridans
 - Alpha-hemolytic streptococcus

Endocarditis Risk Factors

- Melody Valve
- Stent fracture/stenosis
- Hemodialysis
- Homograft

Percutaneous Valves: Future Directions

- Systems to address dilated outflow tracts:
 - Diameters $> 29\text{mm}$
- Use in aortic position
- Use in mitral and tricuspid positions