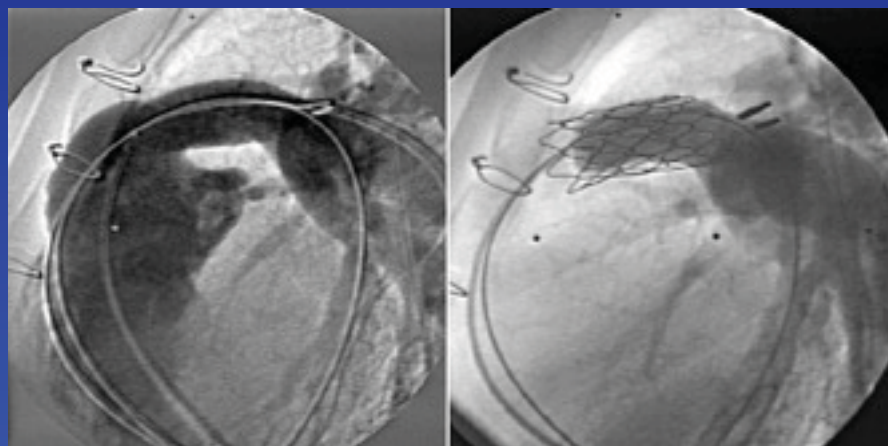


Melody transcatheter pulmonary valve implantation: Tips and tricks

Frank F. Ing, MD
Professor of Pediatrics
Children's Hospital Los Angeles
University of Southern California

Implantable Pulmonary valve

- **MELODY® Transcatheter Pulmonary Valve** is intended to:
 - Relieve conduit stenosis without inducing regurgitation
 - Restore & maintain pulmonary valve competence
- *....with the goal of extending RV to PA conduit life*



Implantable Pulmonary valve

- 18mm modified Contegra bovine jugular vein valve
- Platinum iridium frame
 - 28mm length
 - Crimped down to 6mm, re-expanded 18mm up to 22mm



Melody valve function in a dog model



Results US IDE Study*

Event	Freedom From Event @ 1 year N=136	Freedom From Event @ 2 years
Death	>99%	>99%
Reoperation (Conduit exchange)	>99%	>99%
Catheter Reintervention	93.5%	87.6%
All Stent Fracture	77 22% fracture rate	

Safe

Effective

*McElhinney D, et al. Short and Medium Term Outcomes After Transcatheter Pulmonary Valve Placement in the Expanded Multi-Center US Melody Valve Trial. Circulation 2010;122:507-516.

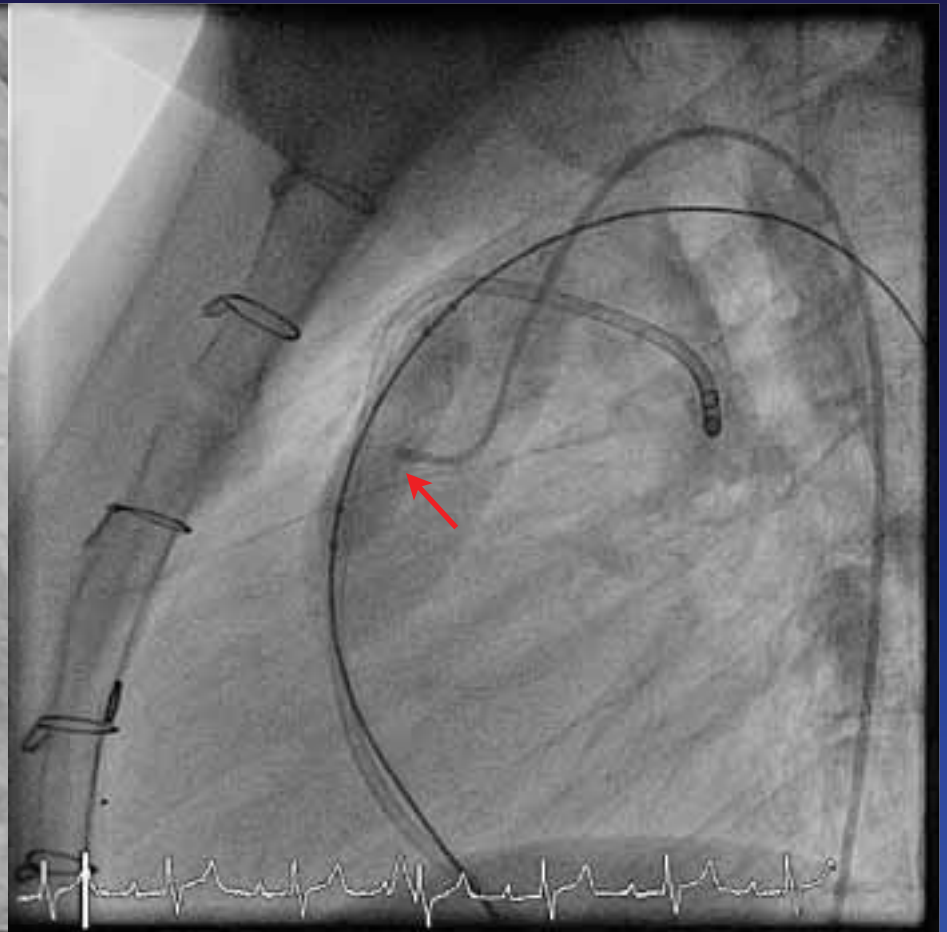
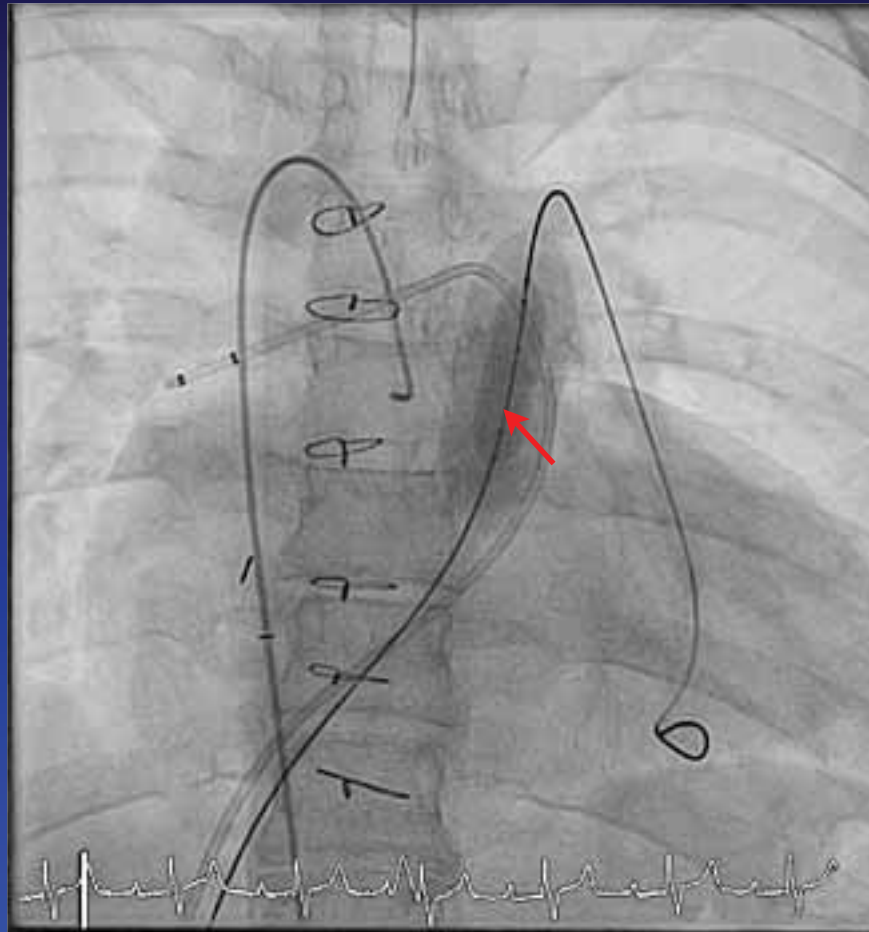
Problems and pitfalls

- **Beware of coronary artery compression**
- **Melody valve stent fracture**
 - Pre-stenting prior to Melody valve implant
- **Conduit issues:**
 - Calcified conduits; dissections and ruptures
 - Angulated conduits
 - Extending limits of homografts
- **Venous/IJ access issues**
- **“Figure of 8” stitch for venous hemostasis**
- **Post Melody implant**
 - Arrhythmias
 - Endocarditis issues
- **Melody valve implant in other positions**

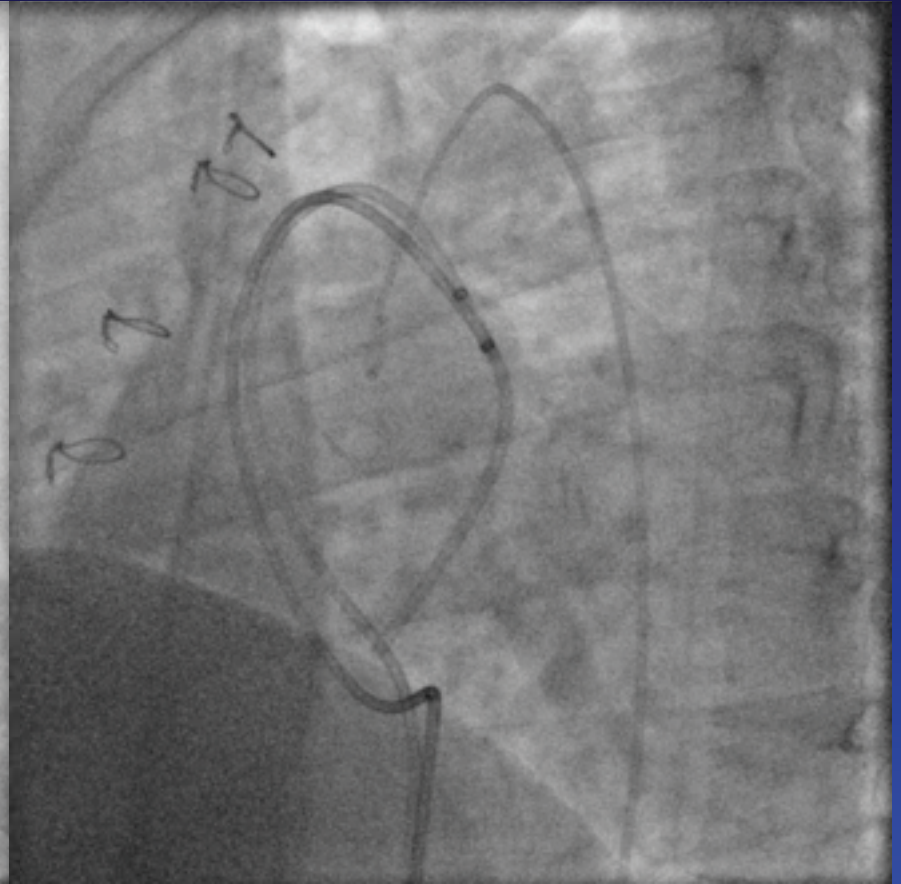
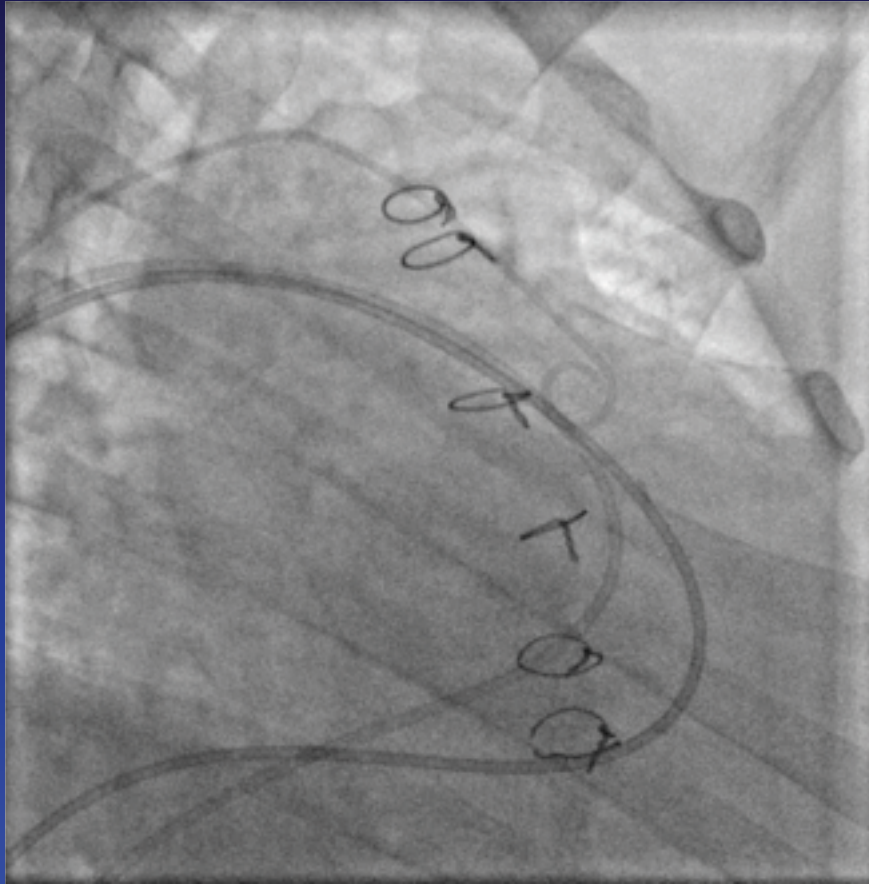
Balloon testing for coronary compression

- Tip:
 - Keep contrast in balloon dilute (1:5 or 1:6 dilution)- to see coronary compression superimposed over balloon
 - If in doubt, repeat angiogram using different angulations; rotational angiography

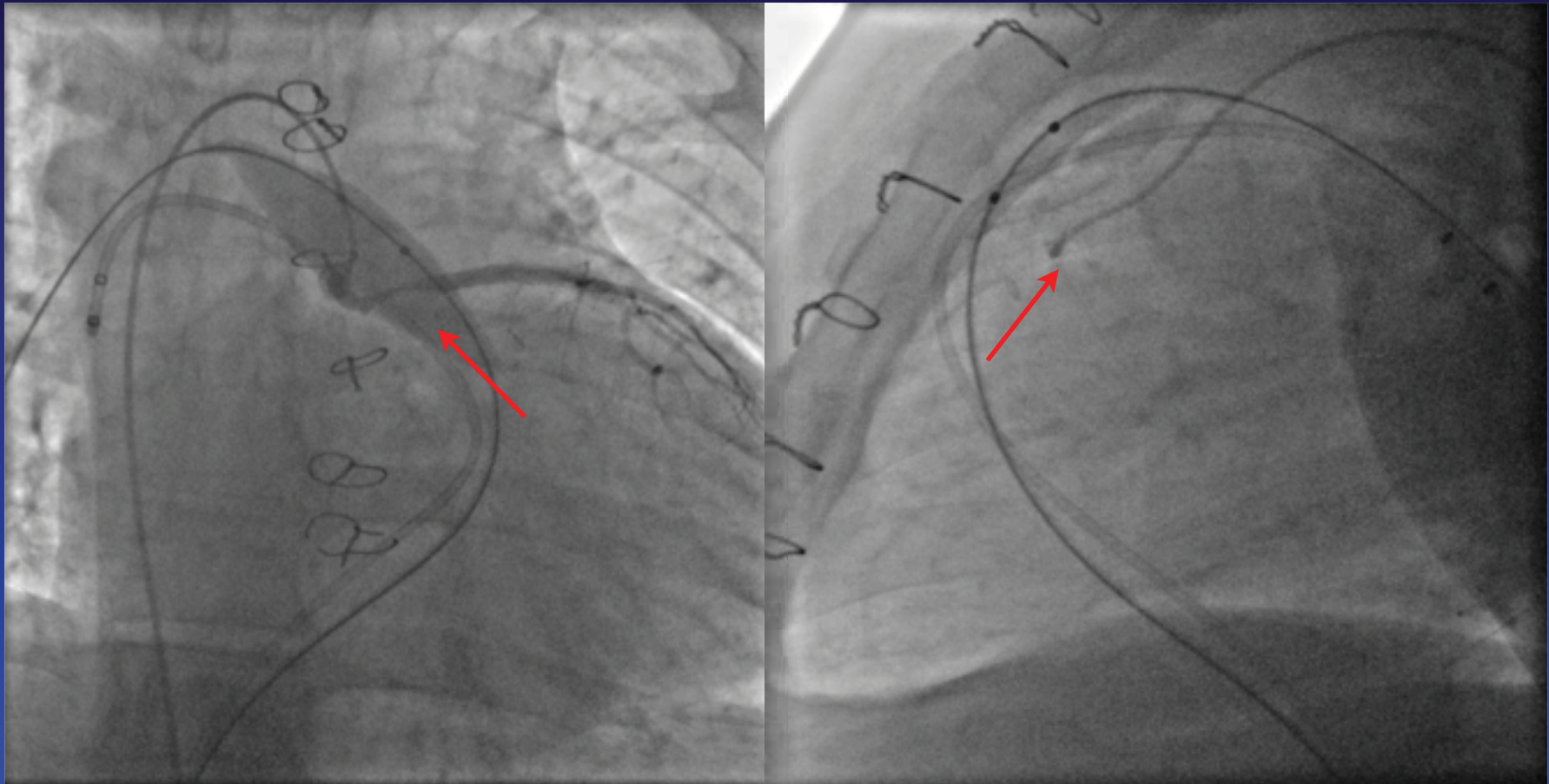
Use 1:5 or 6 dilution of contrast for balloon testing



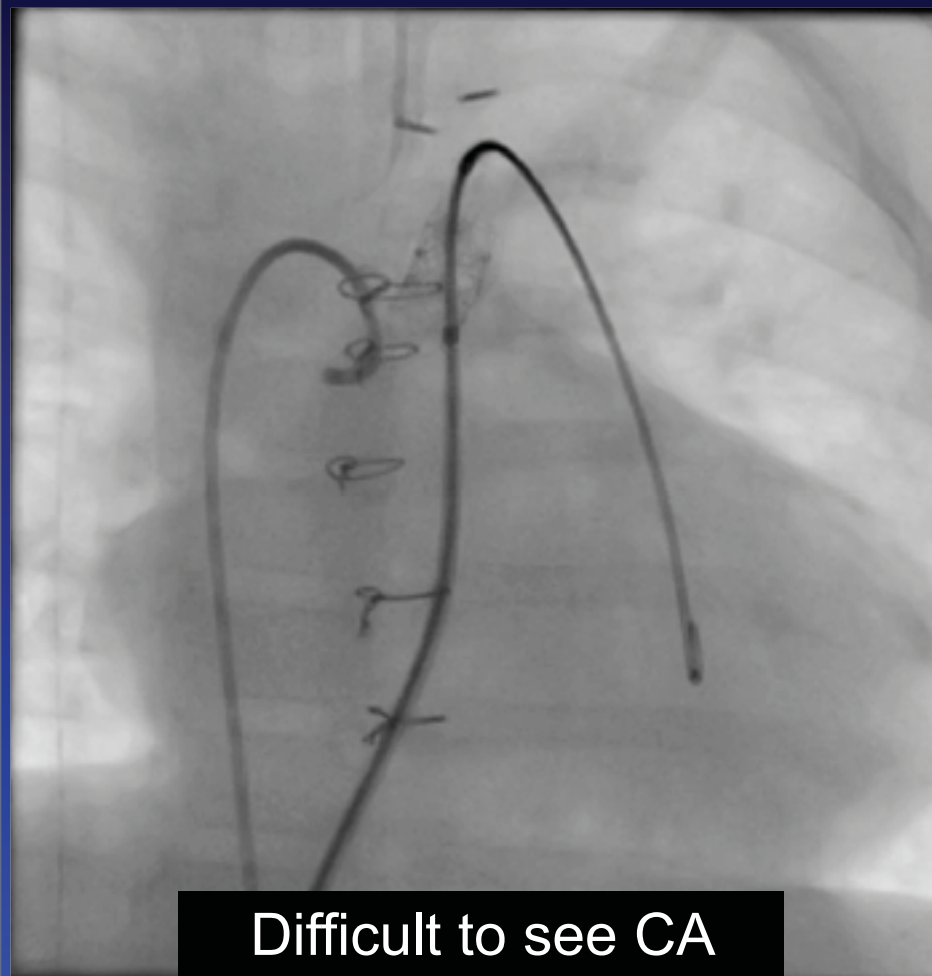
Aortogram- CA course not clear



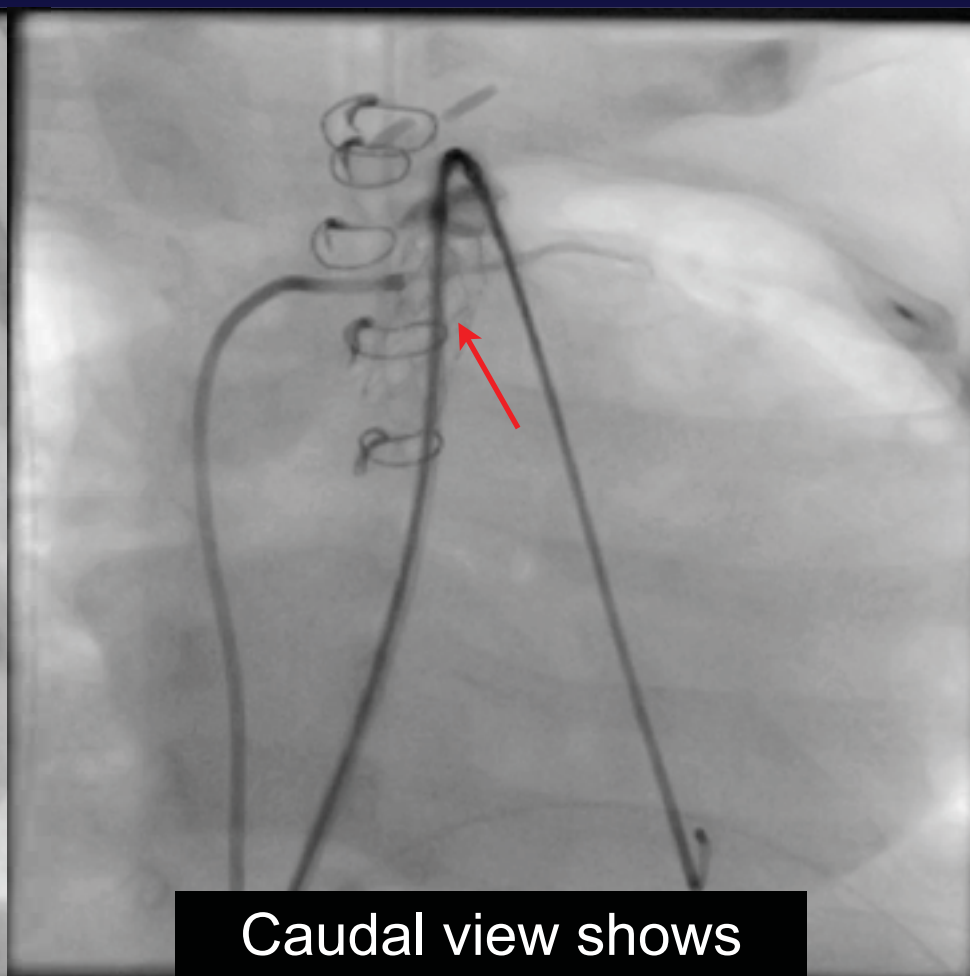
Balloon test inflation: LAD off right coronary sinus



Cononary artery compression

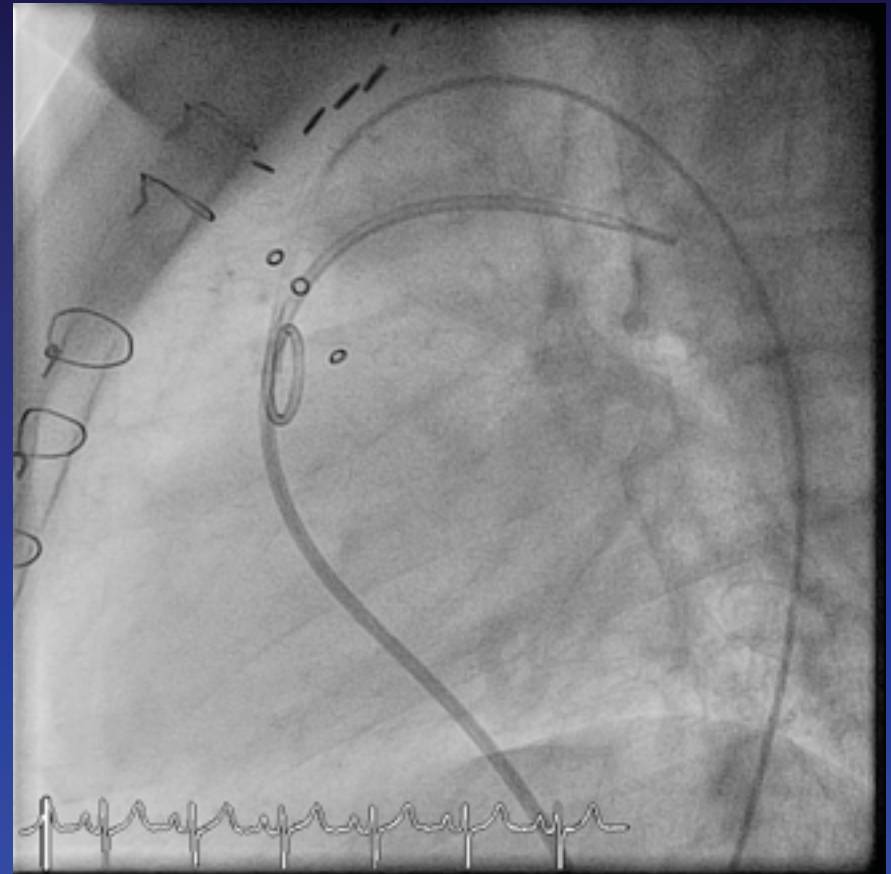
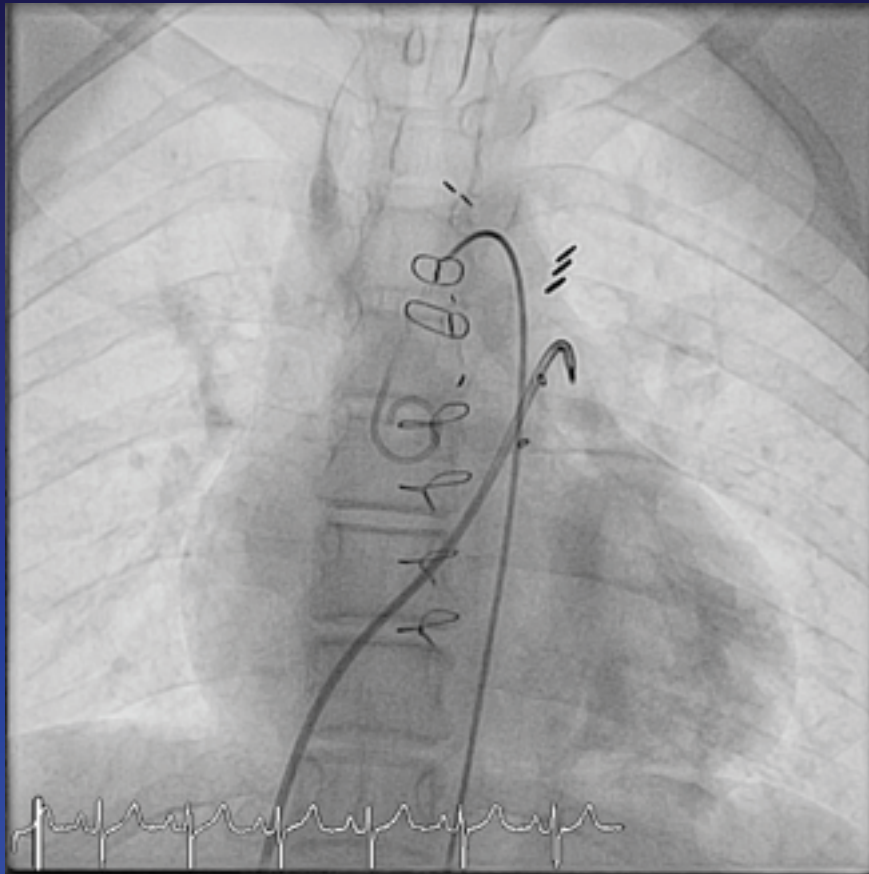


Difficult to see CA
with dark balloon



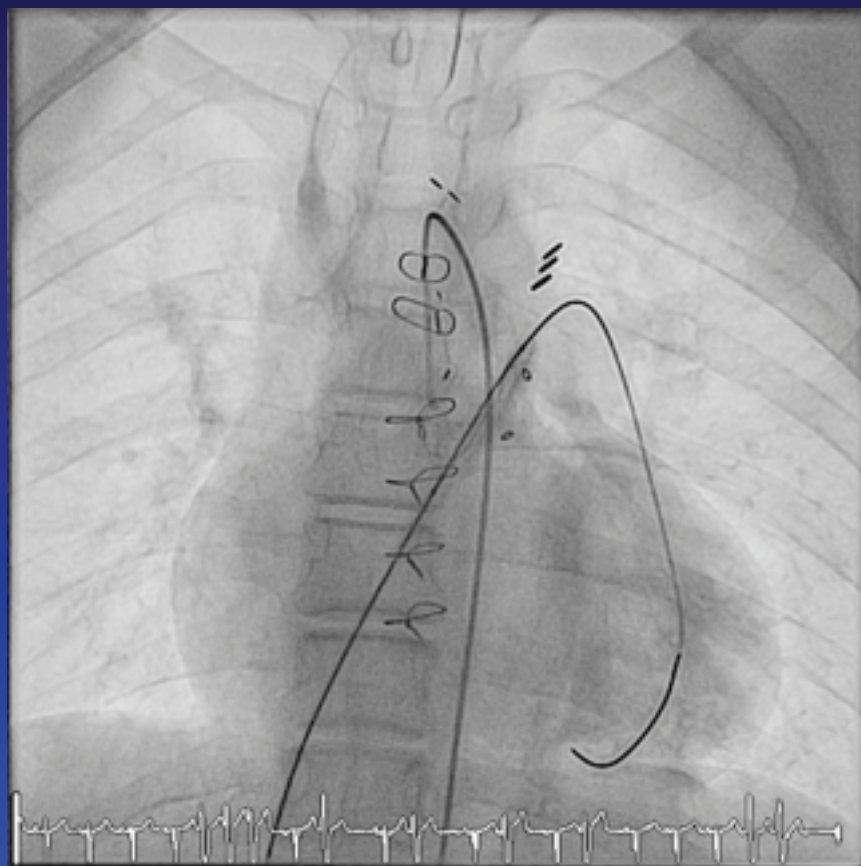
Caudal view shows
CA under Balloon

Aortogram: Coronary artery unclear

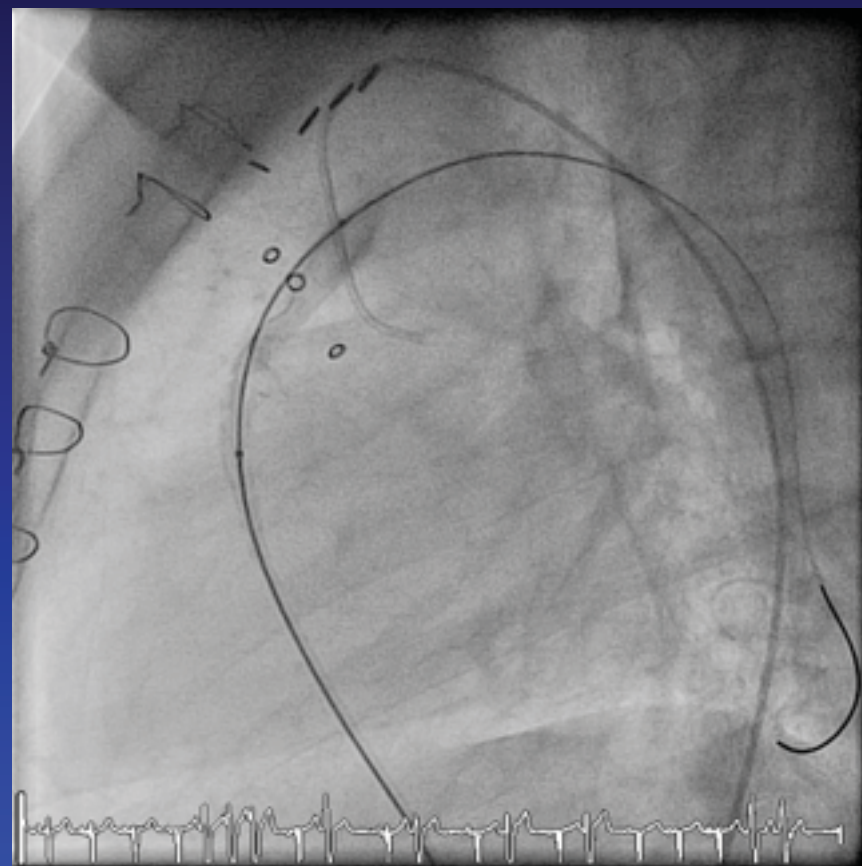


Balloon testing: CA compression not always obvious even with selective angiogram

AP

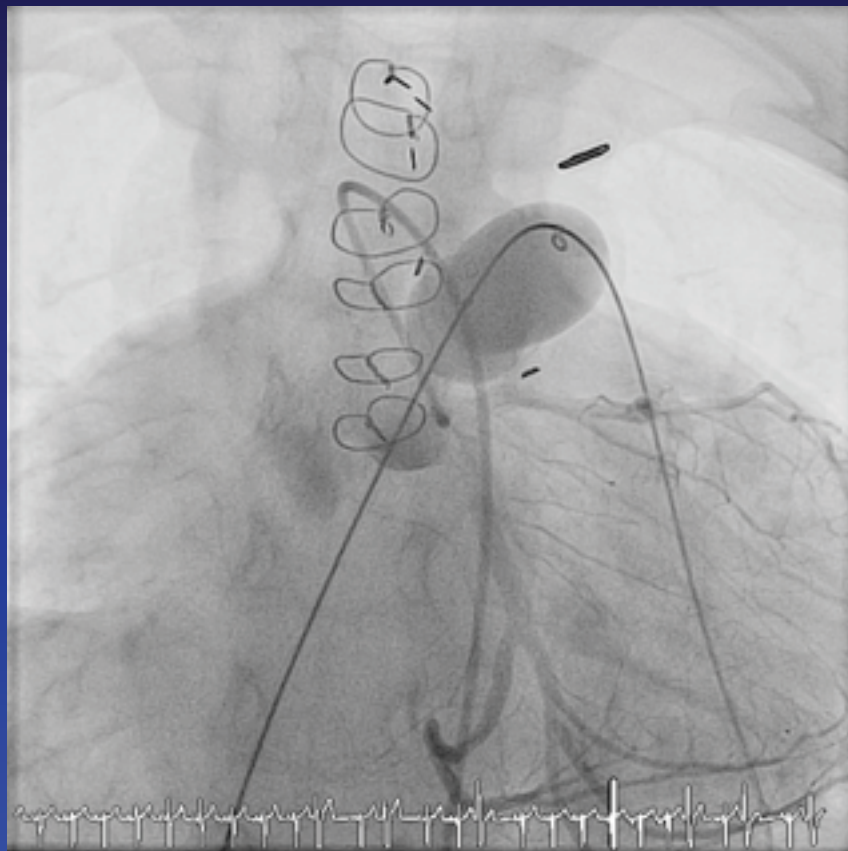


Lat

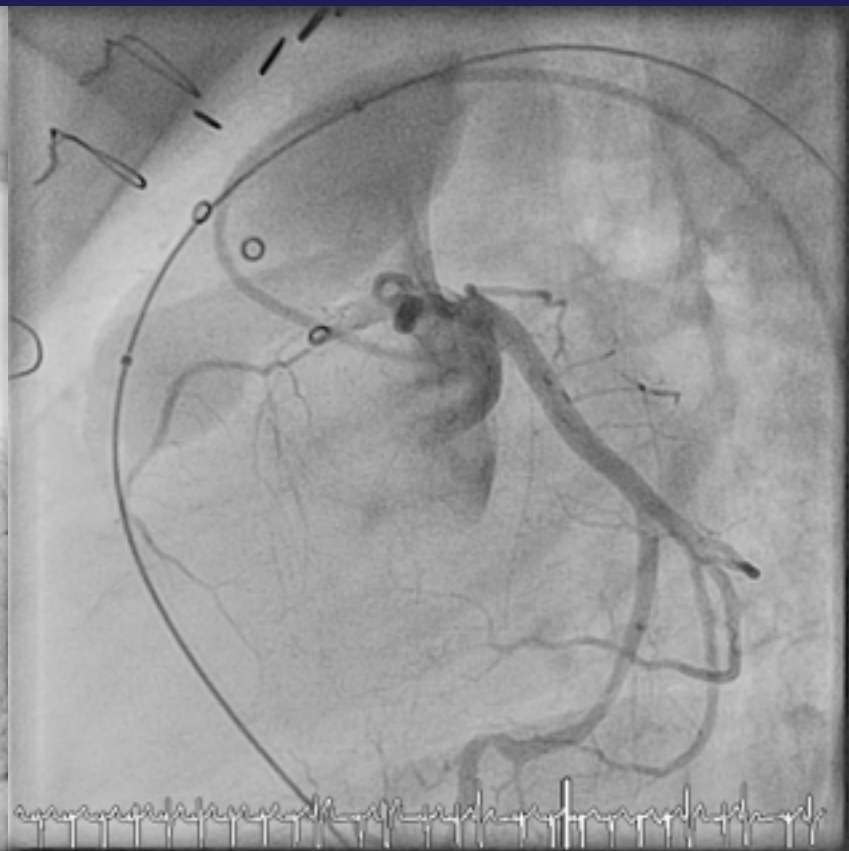


Repeat balloon testing and angiography with new angulation

AP-Cau 32



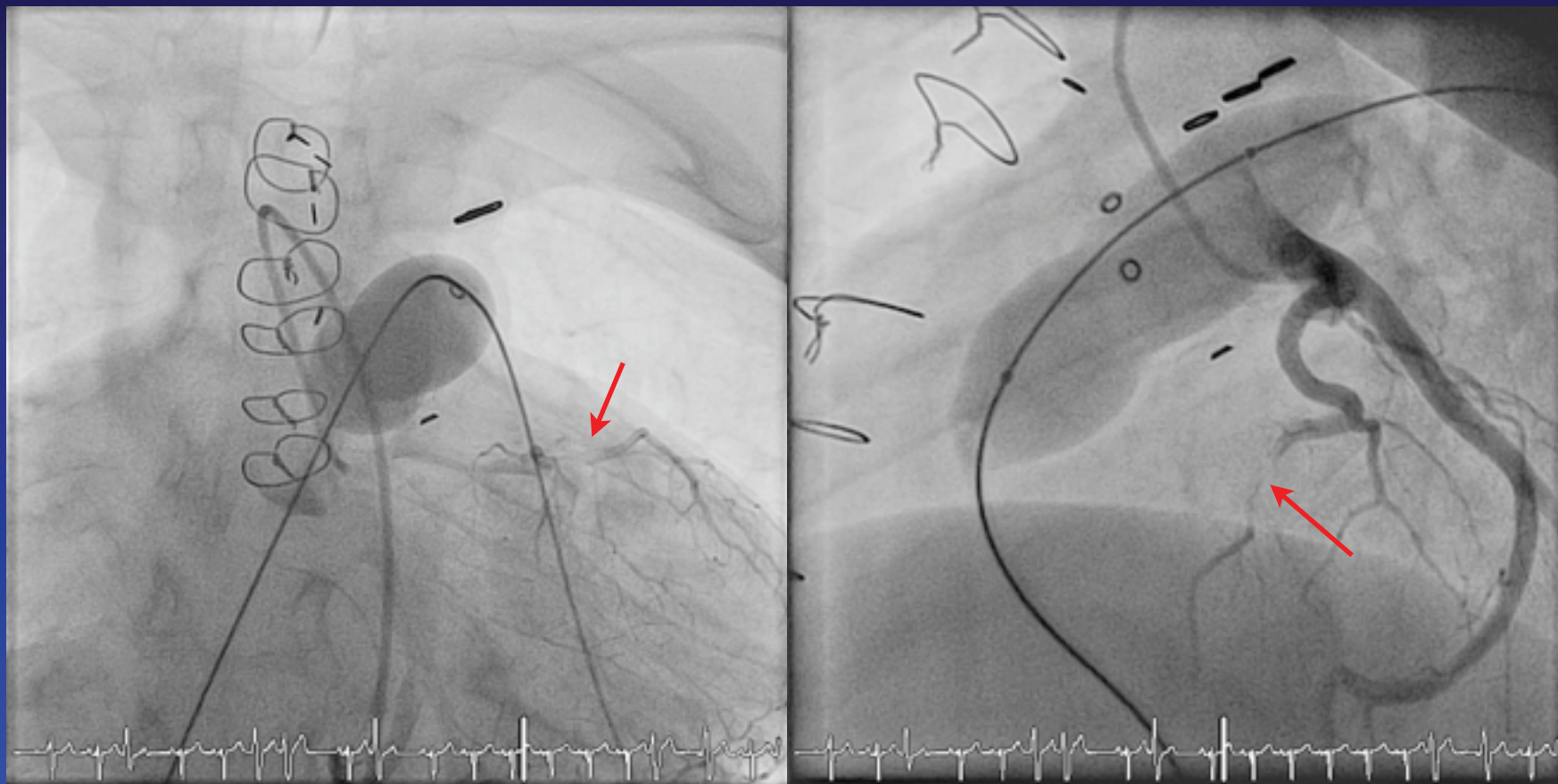
Lat-Cra 15



Repeat balloon testing with new angulation

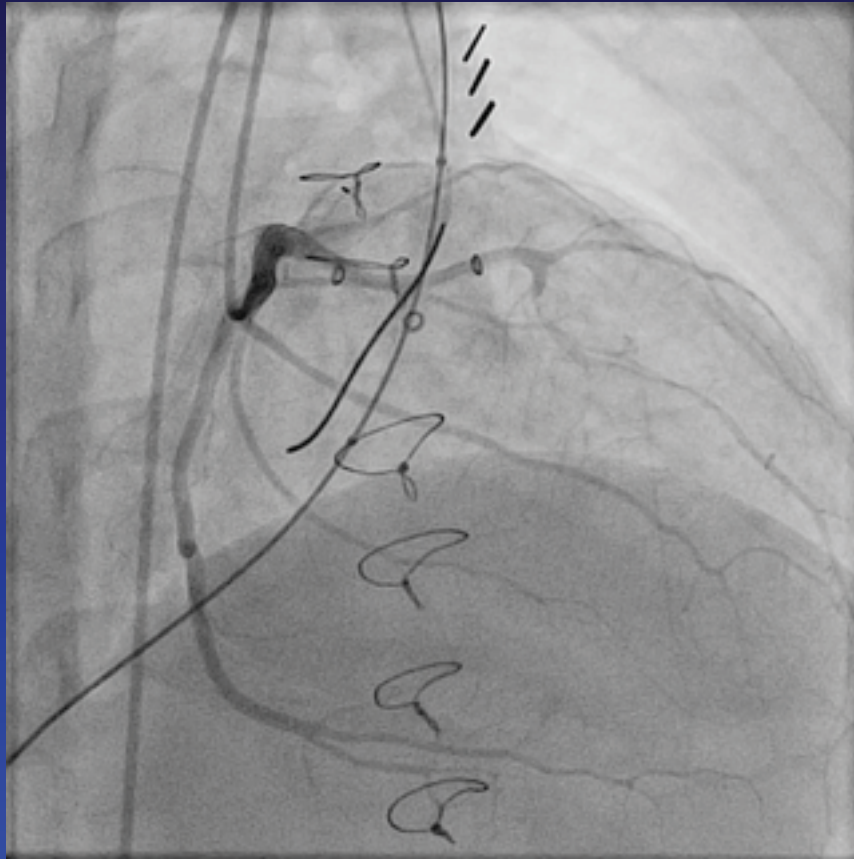
AP-Cau 32

Lat-Lao 66, Cra 18

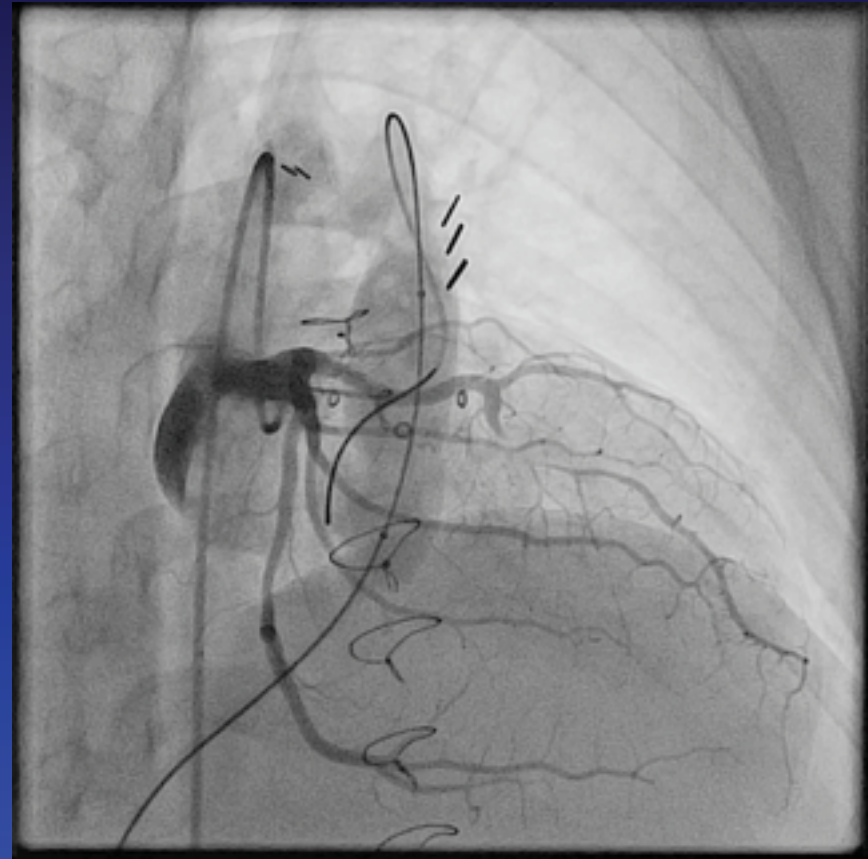


Coronary compression far from balloon

Rotational angiography



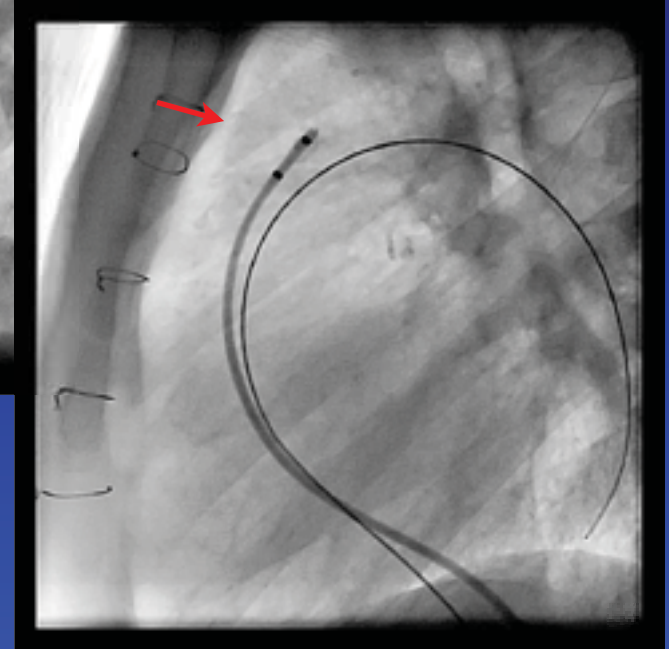
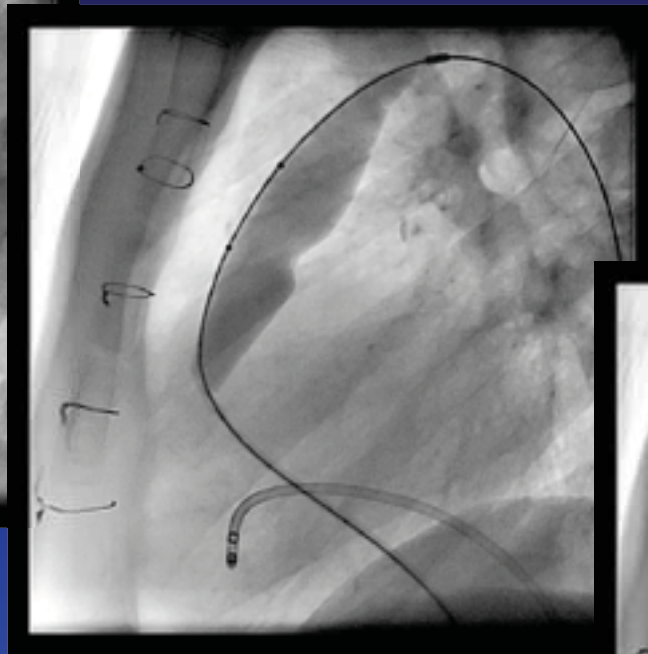
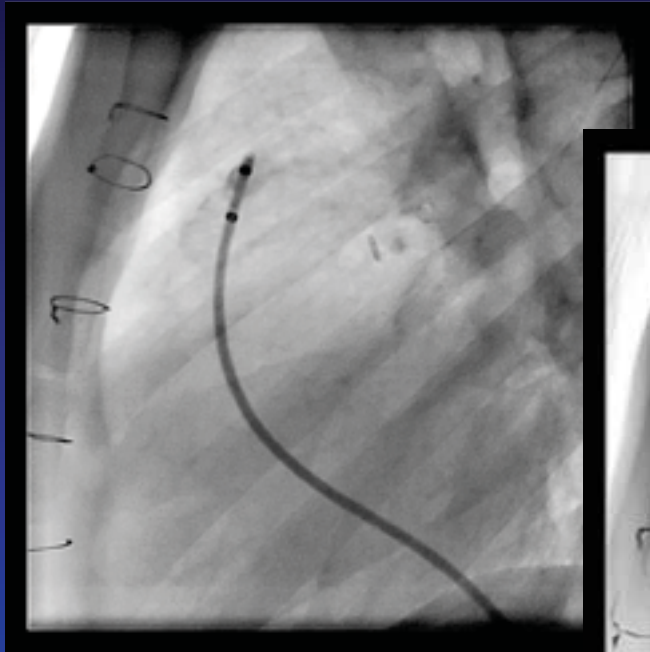
Balloon down



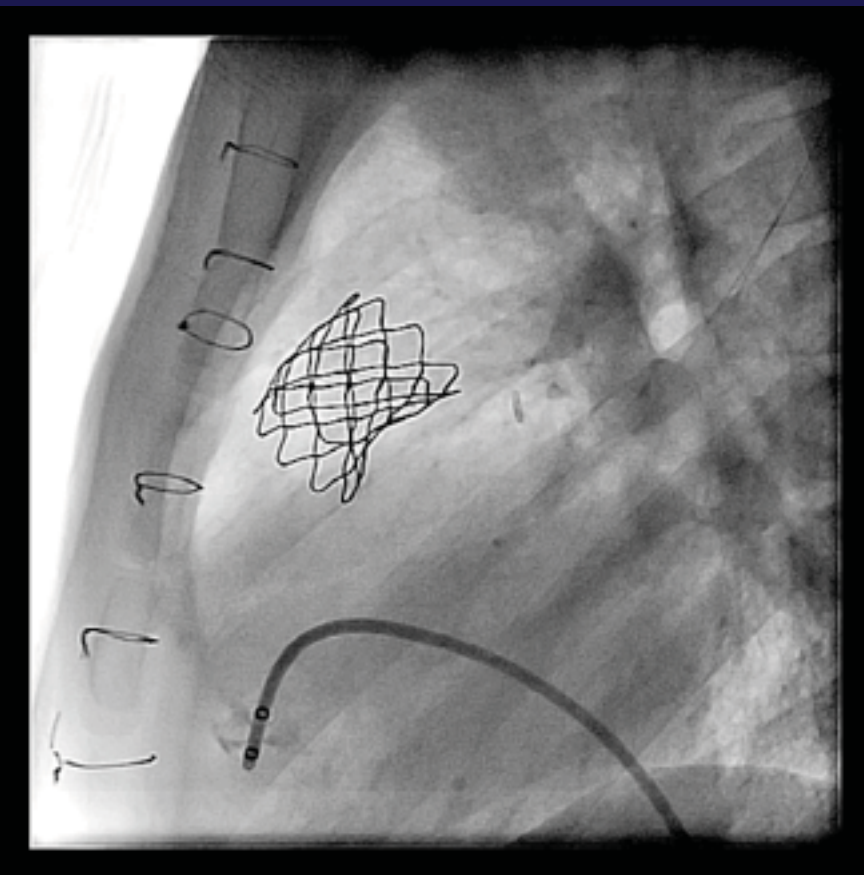
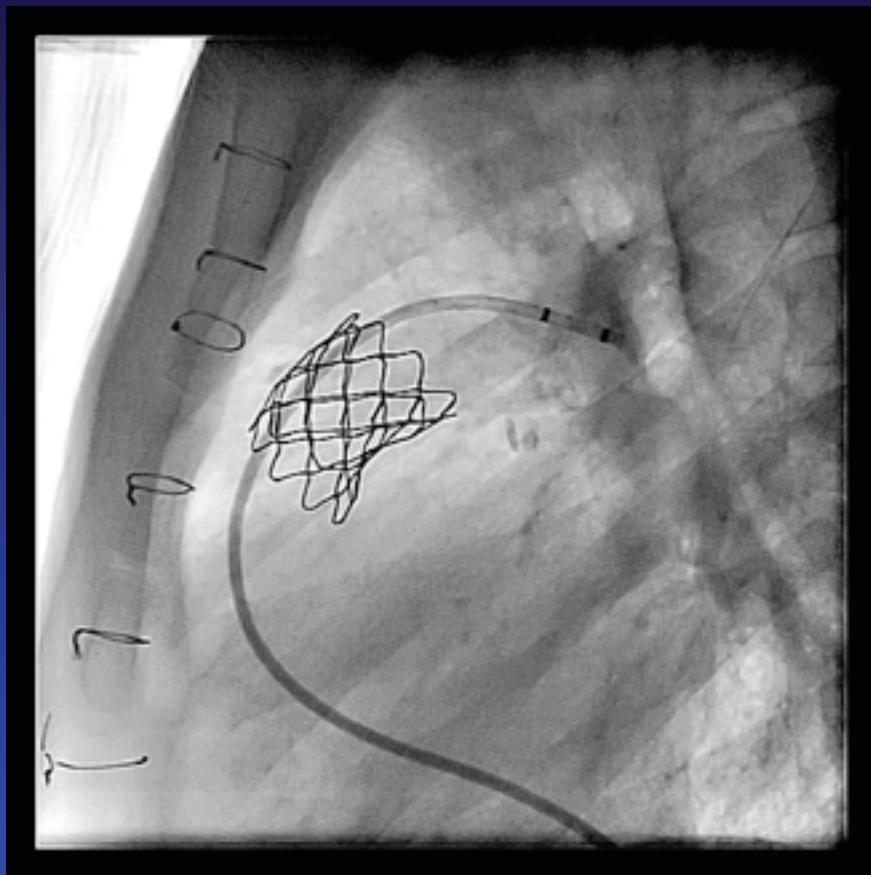
Balloon up: mid-LAD compression

- Beware of coronary artery compression
- **Melody valve stent fracture**
 - **Pre-stenting prior to Melody valve implant**
- Conduit issues:
 - Calcified conduits; dissections and ruptures
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 - Extending limits of homografts
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- **Post Melody implant**
 - Arrhythmias
 - Endocarditis issues
- Melody valve implant in other positions

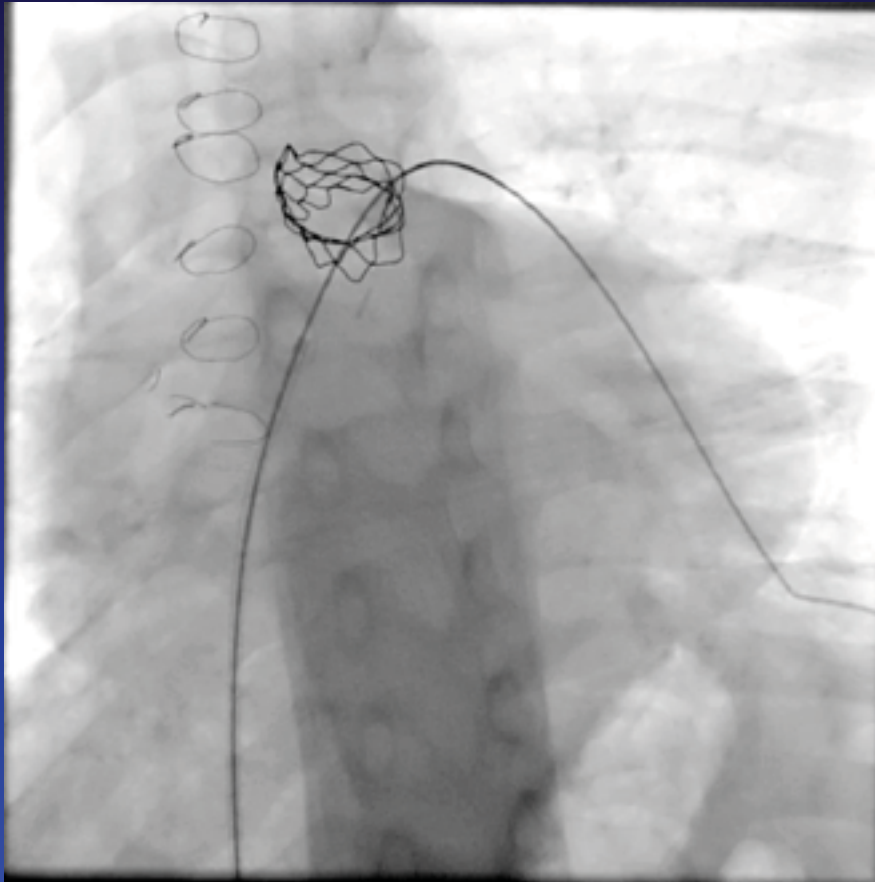
Conduit stenosis



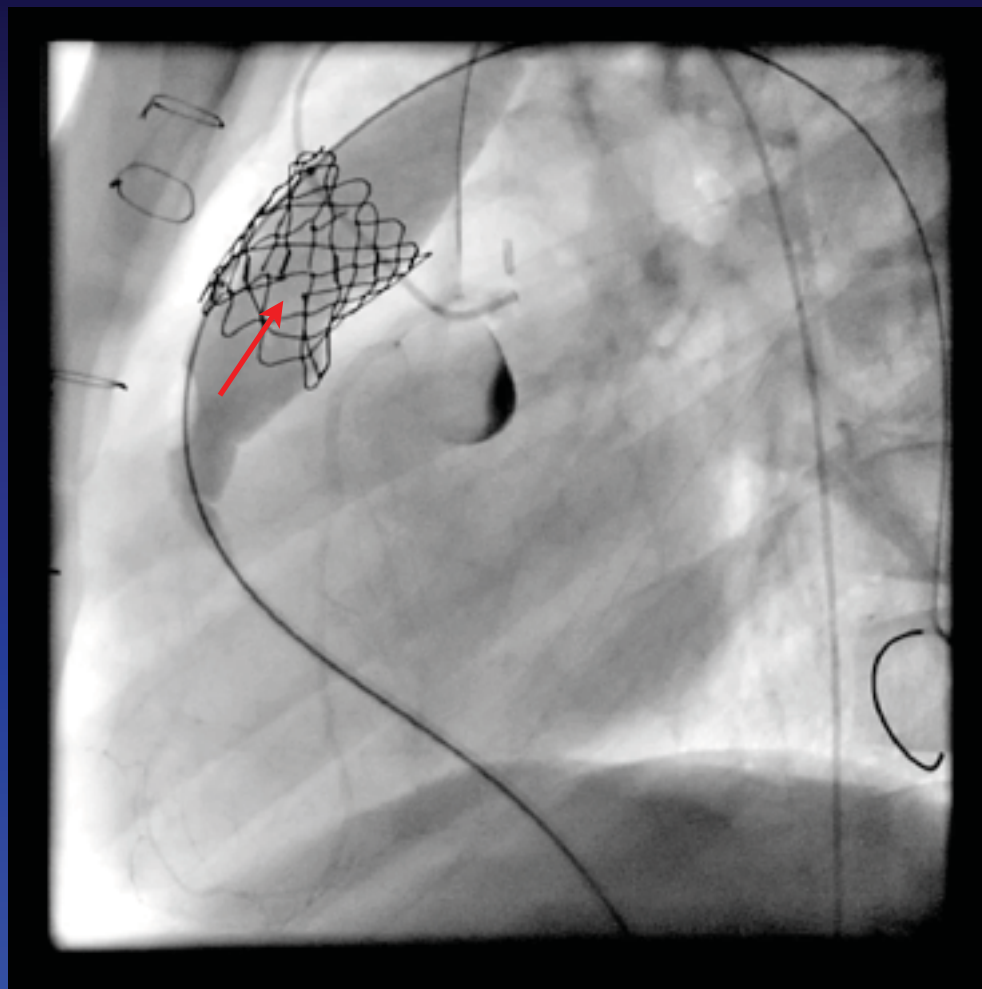
Post Melody implant



6 month later...

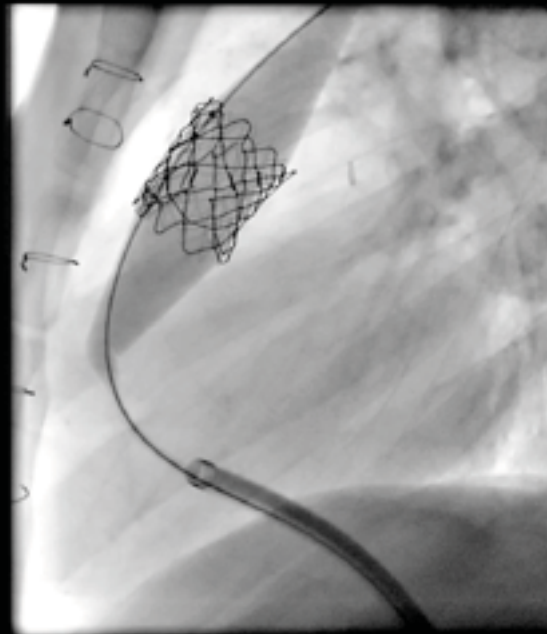


Melody valve stent fractures

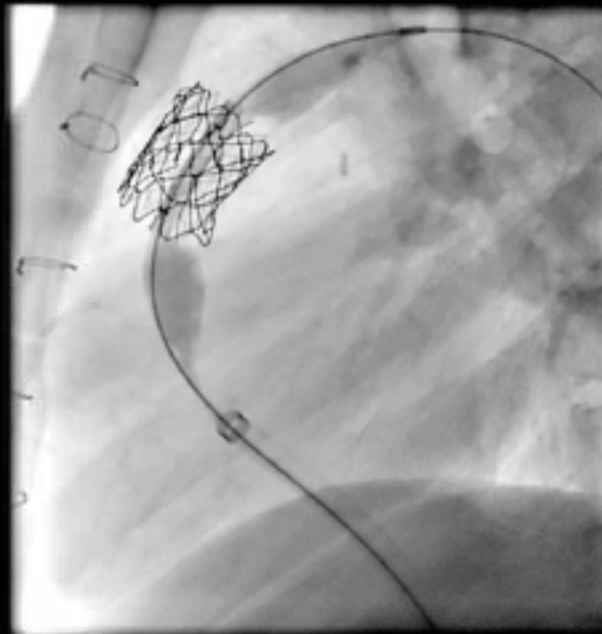


Reinforce with additional stents

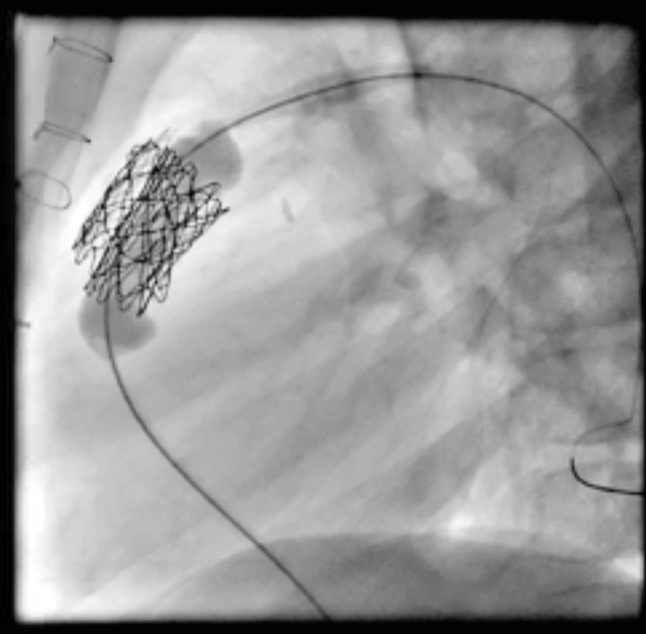
Stent #1



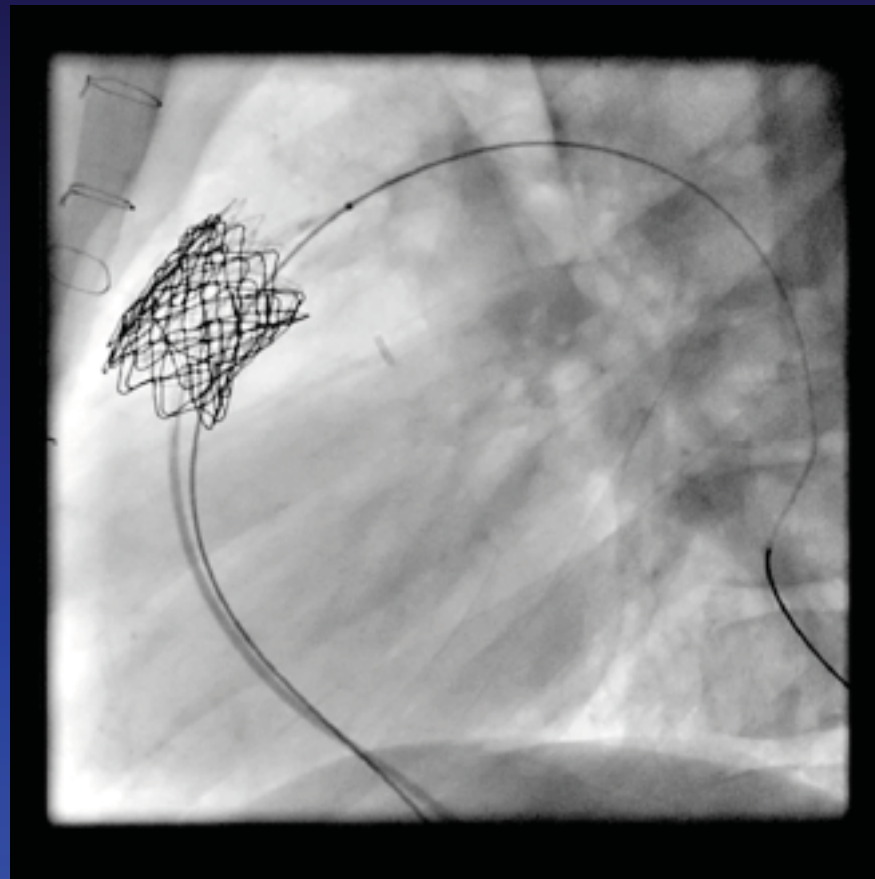
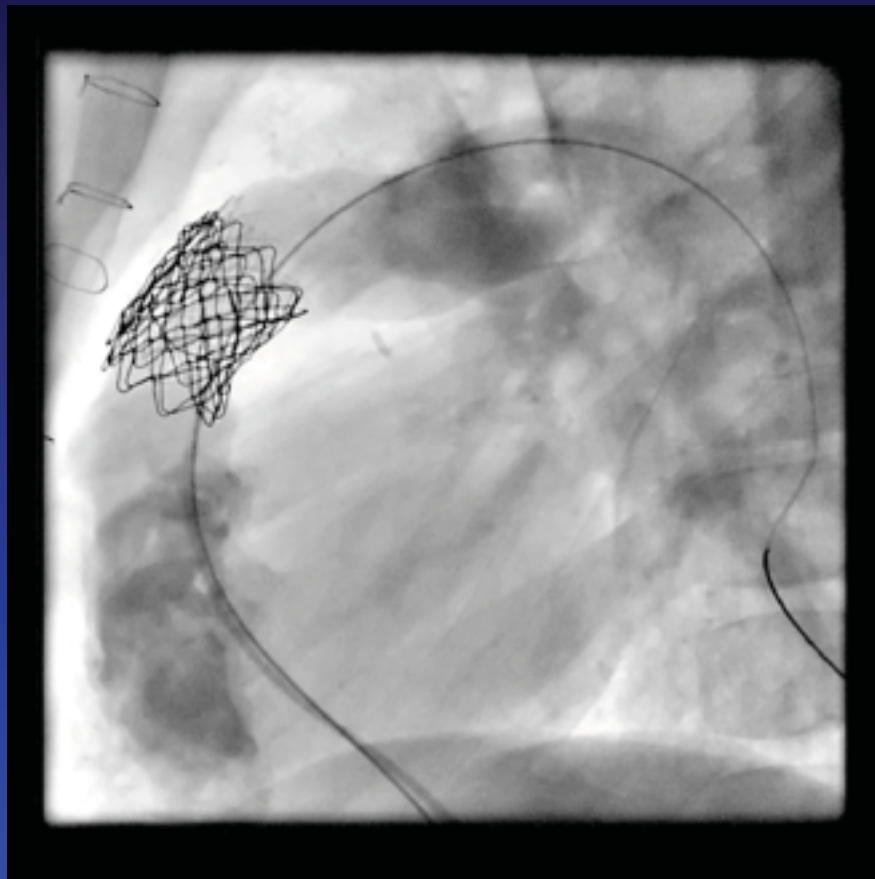
Stent #2



Second Melody valve



Post Melody implant



Subtle fracture may not be seen on CXR, but needs flourosocopy

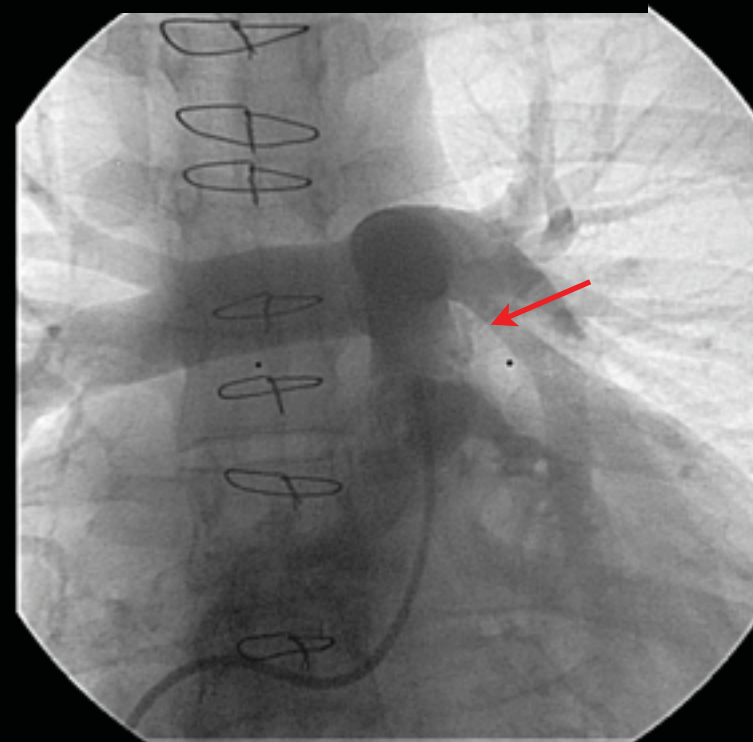
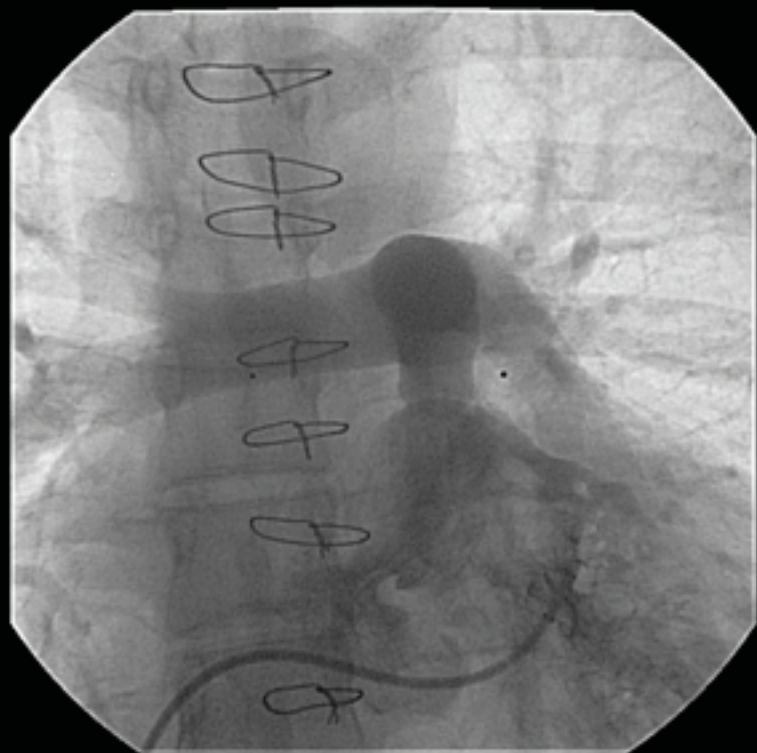


Melody implanted in bioprosthetic valve

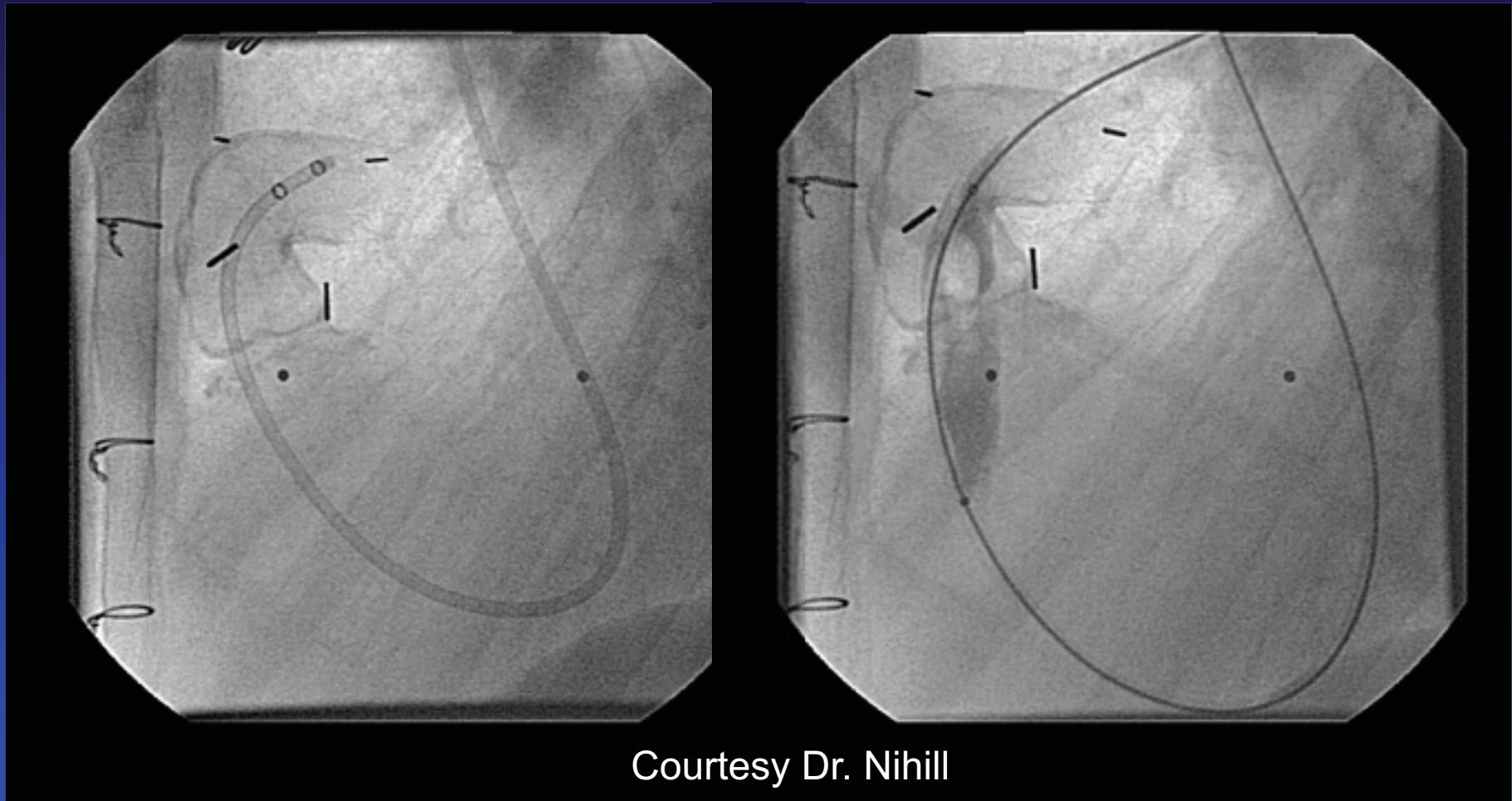
- Beware of coronary artery compression
- Melody valve stent fracture
 - Pre-stenting prior to Melody valve implant
- **Conduit issues:**
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 - **Angulated conduits**
 - **Extending limits of homografts**
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- “Figure of 8” stitch for venous hemostasis
- **Post Melody implant**
 - Arrhythmias
 - Endocarditis issues
- Melody valve implant in other positions

Complications: Dissections

Contained dissection

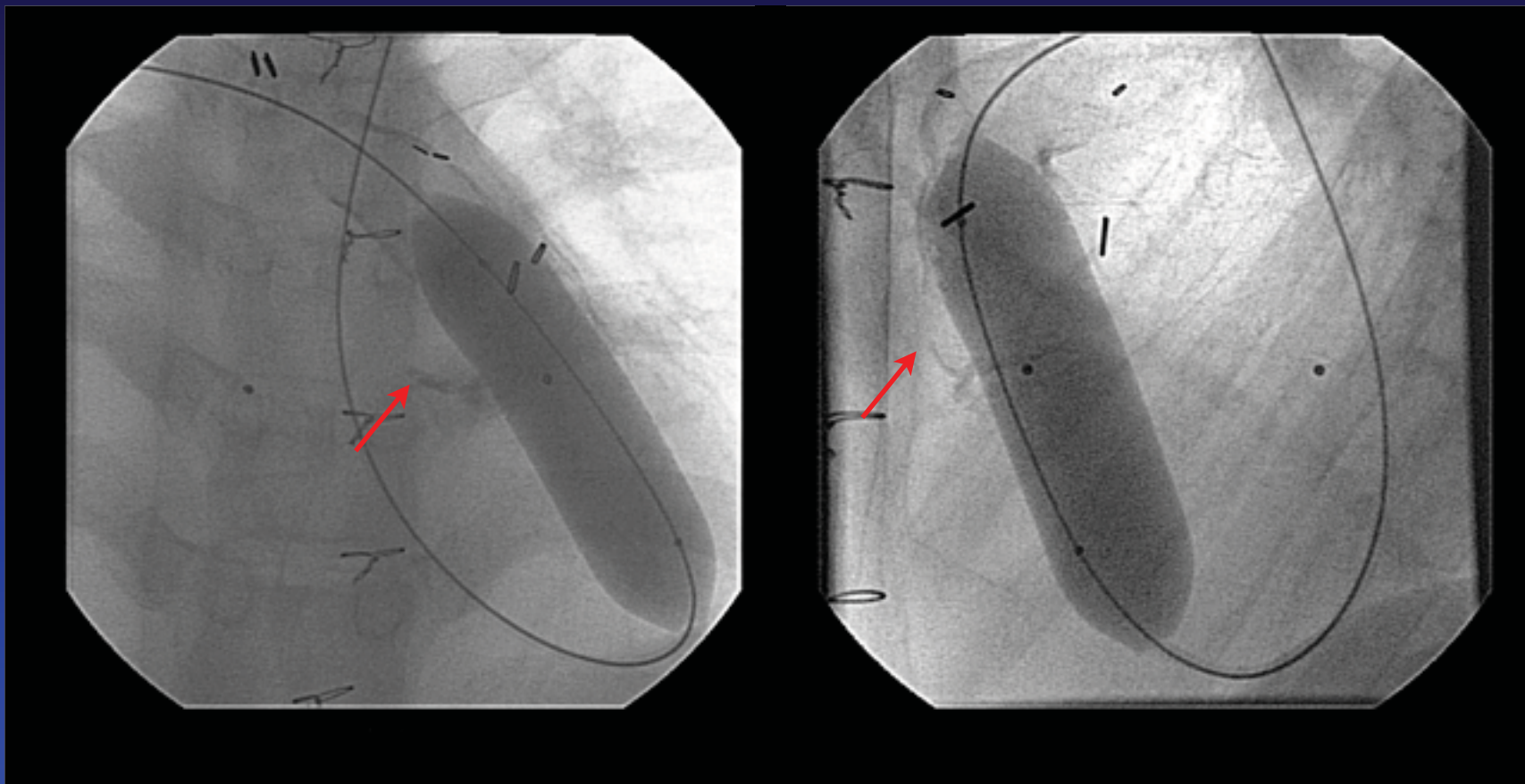


Heavily calcified conduit

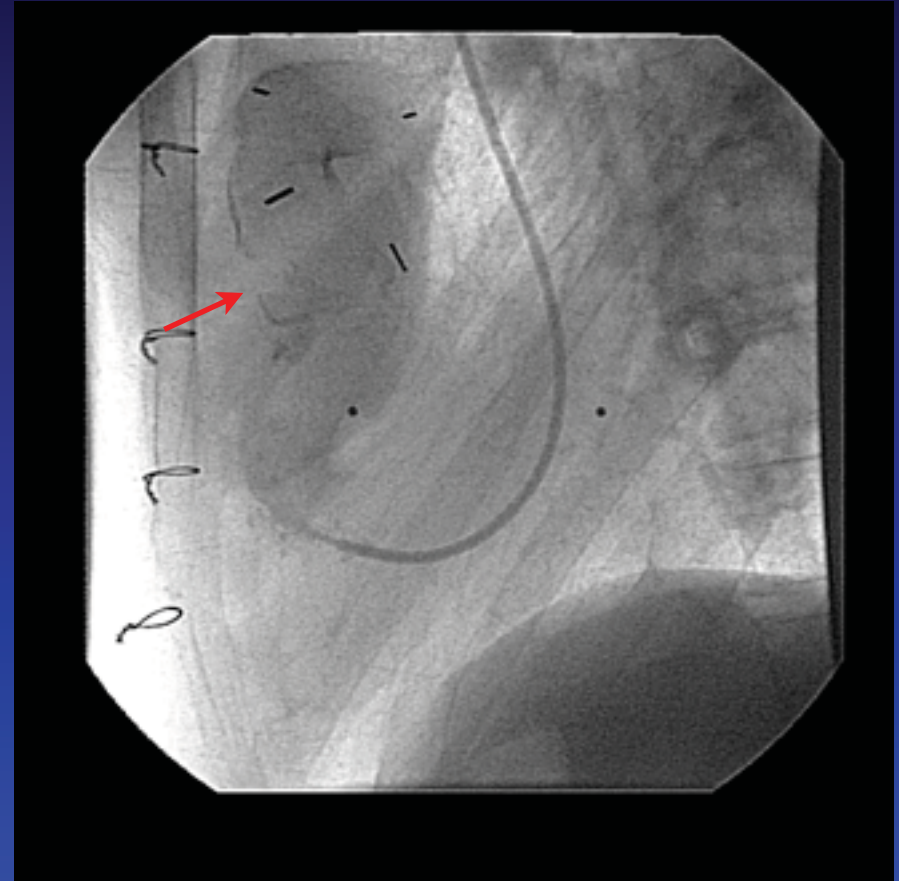
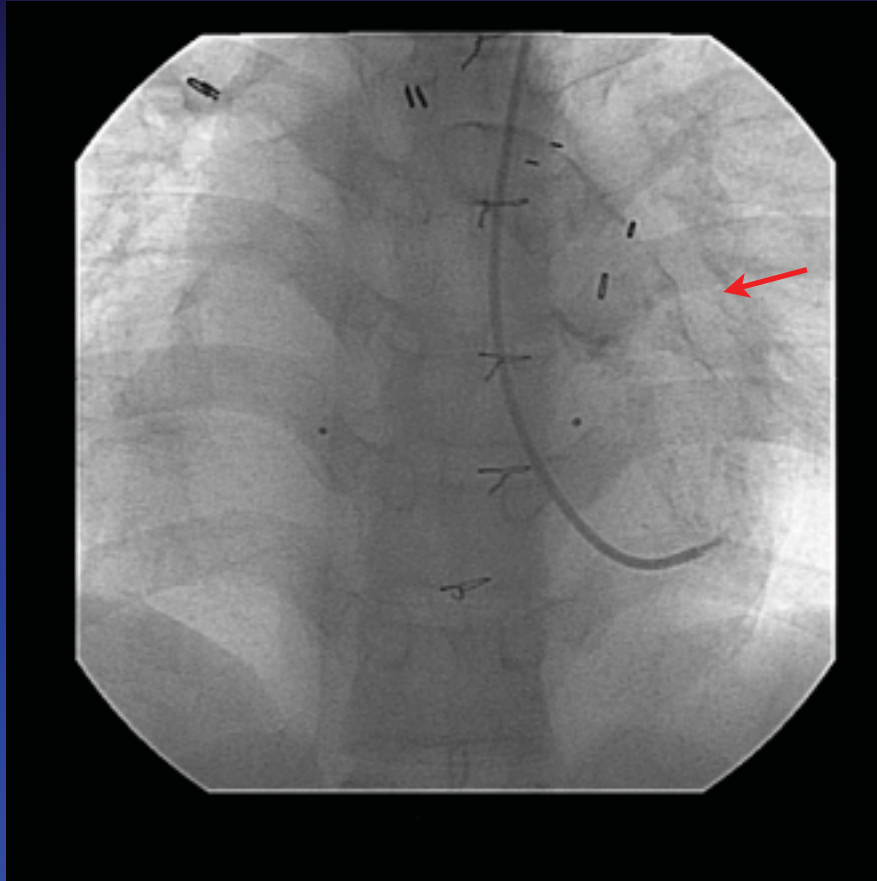


Courtesy Dr. Nihill

Calcified conduit rupture



Post dilation angiogram: Extravasation of contrast



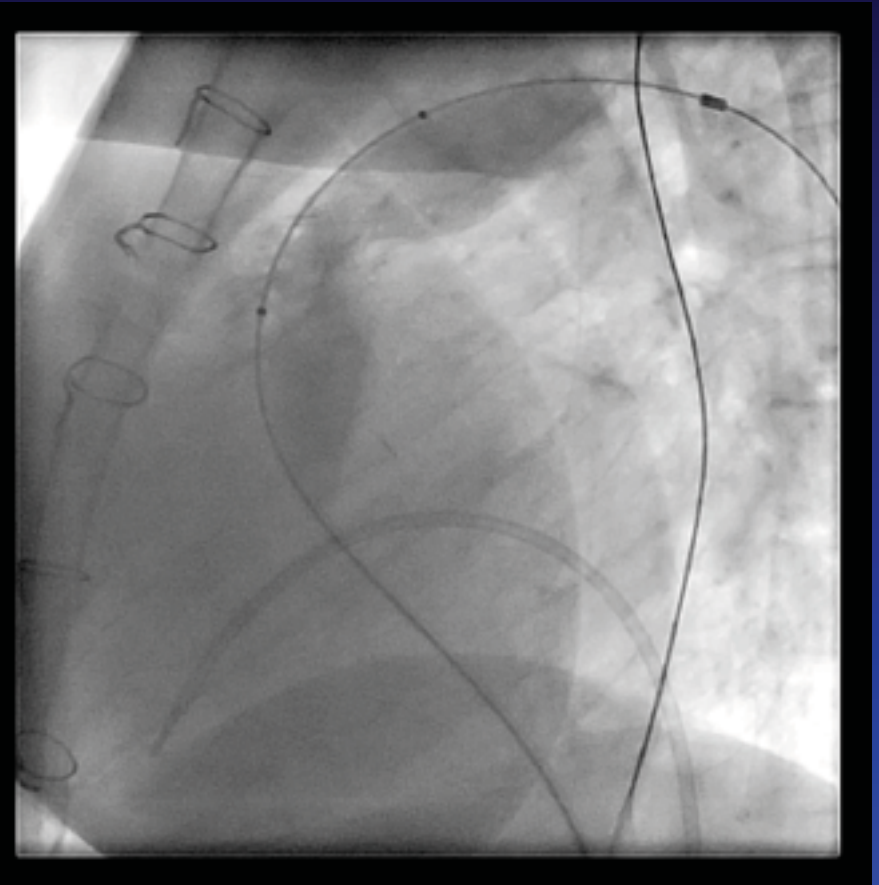
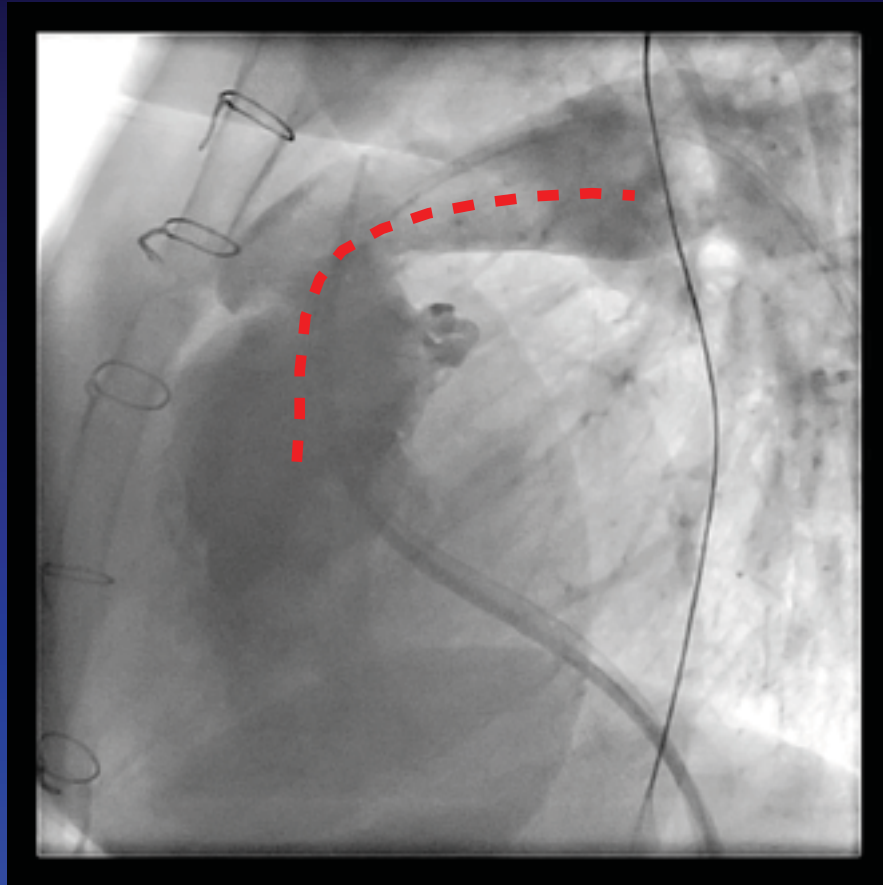
Covered stents



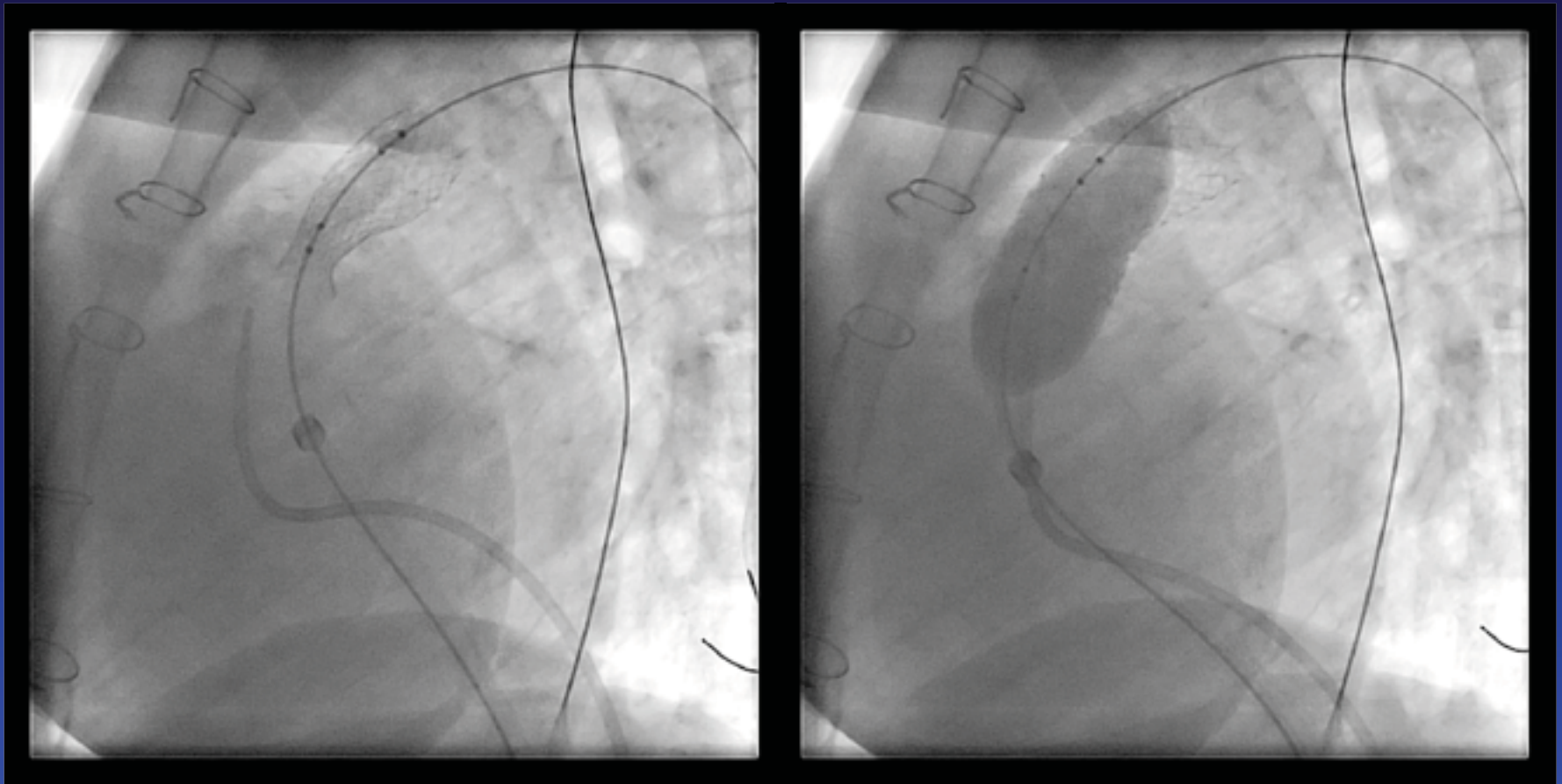
COAST II trial
PARCS trial



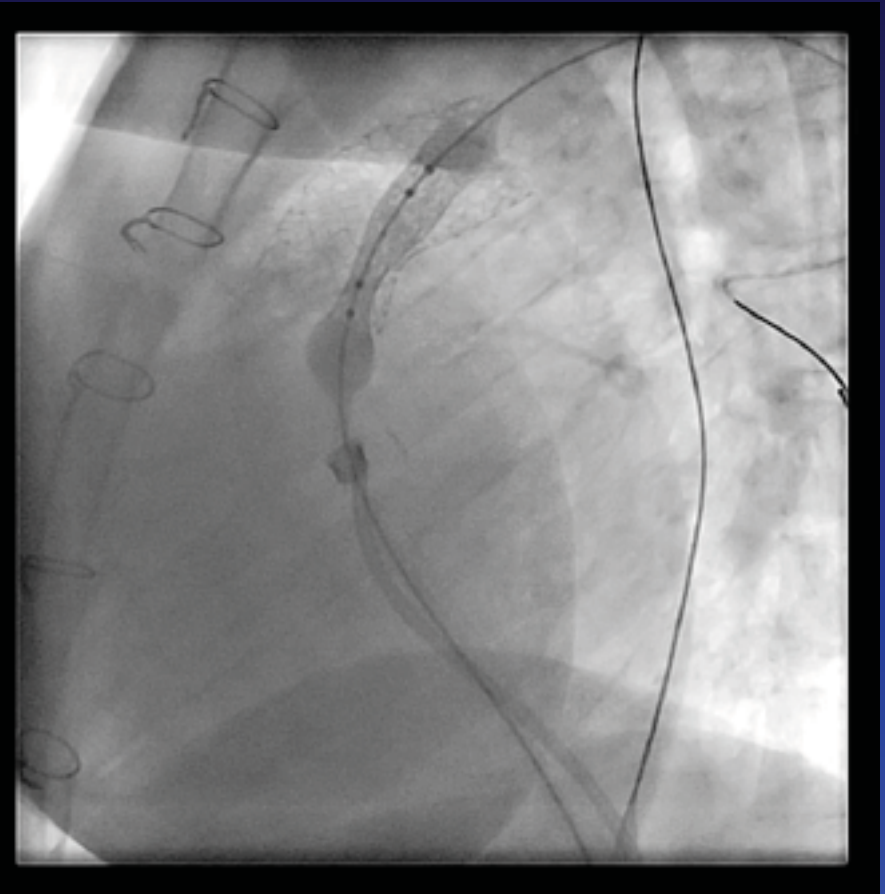
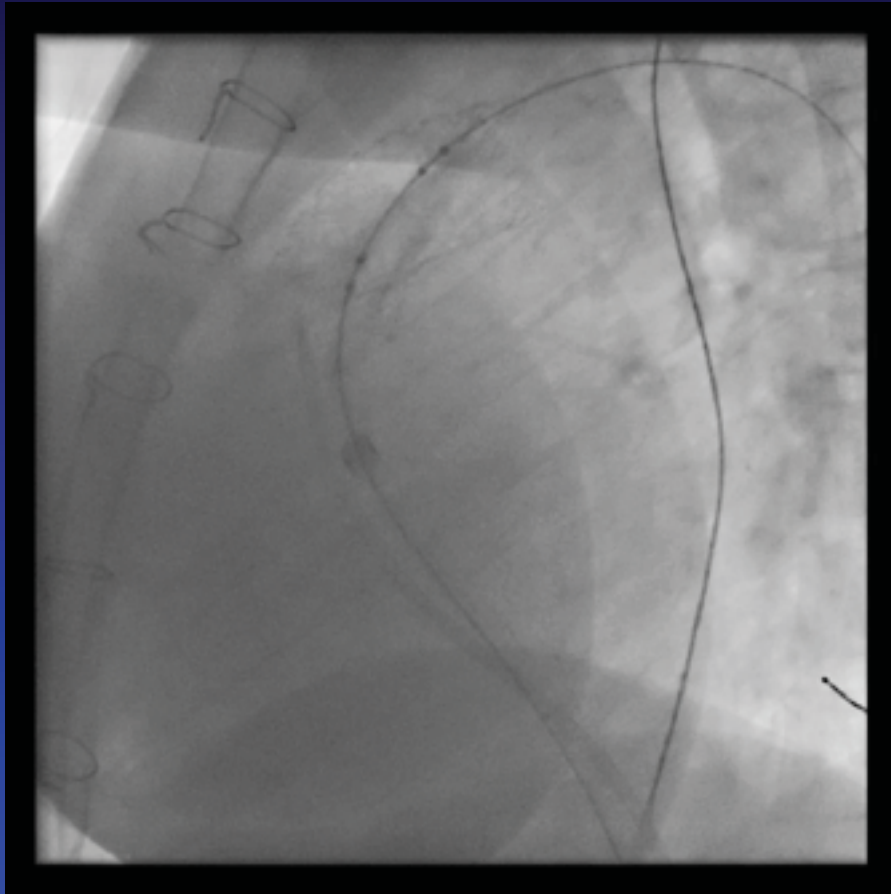
Angulated conduits



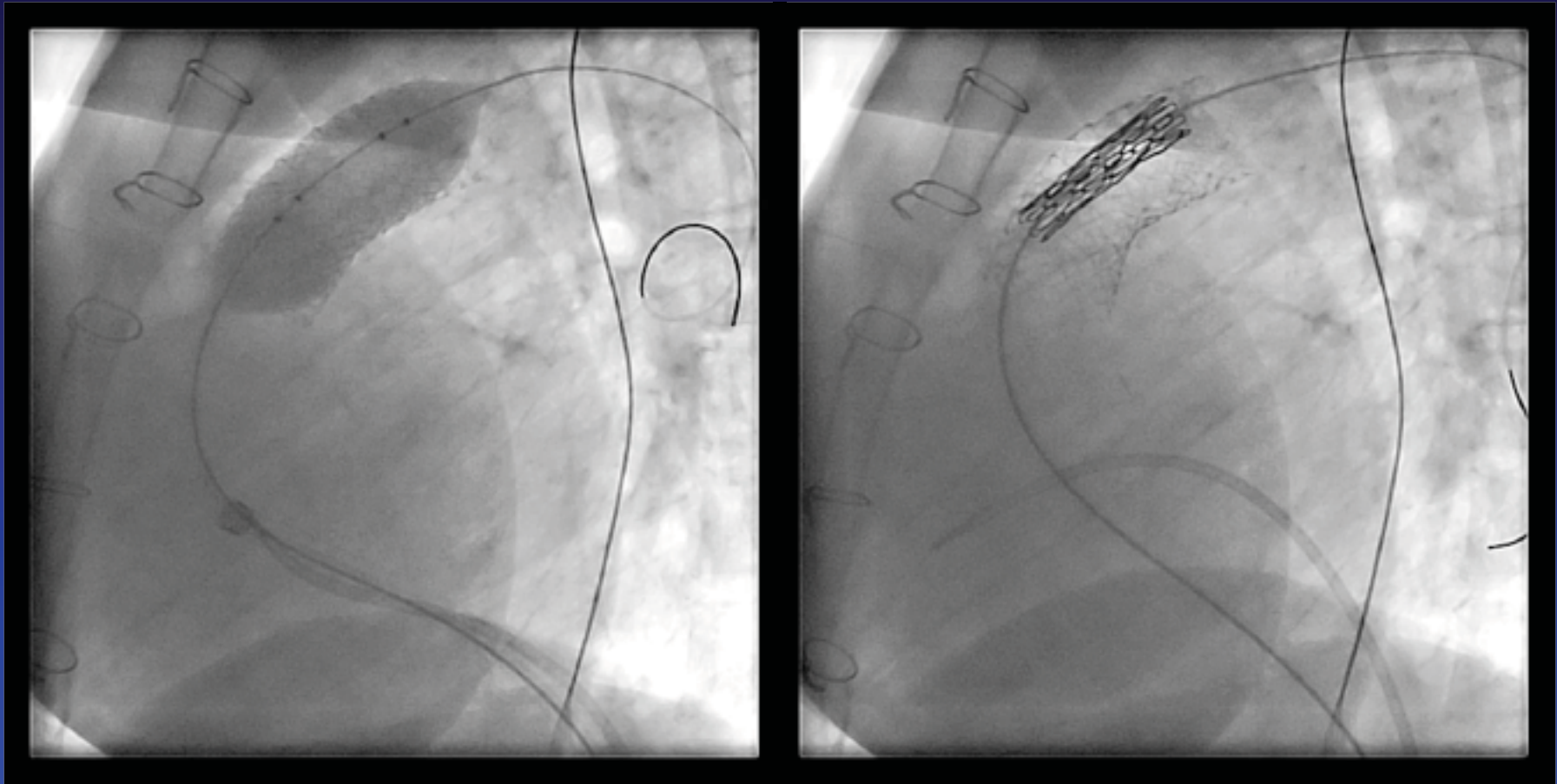
Implanting Maxi-LD stent



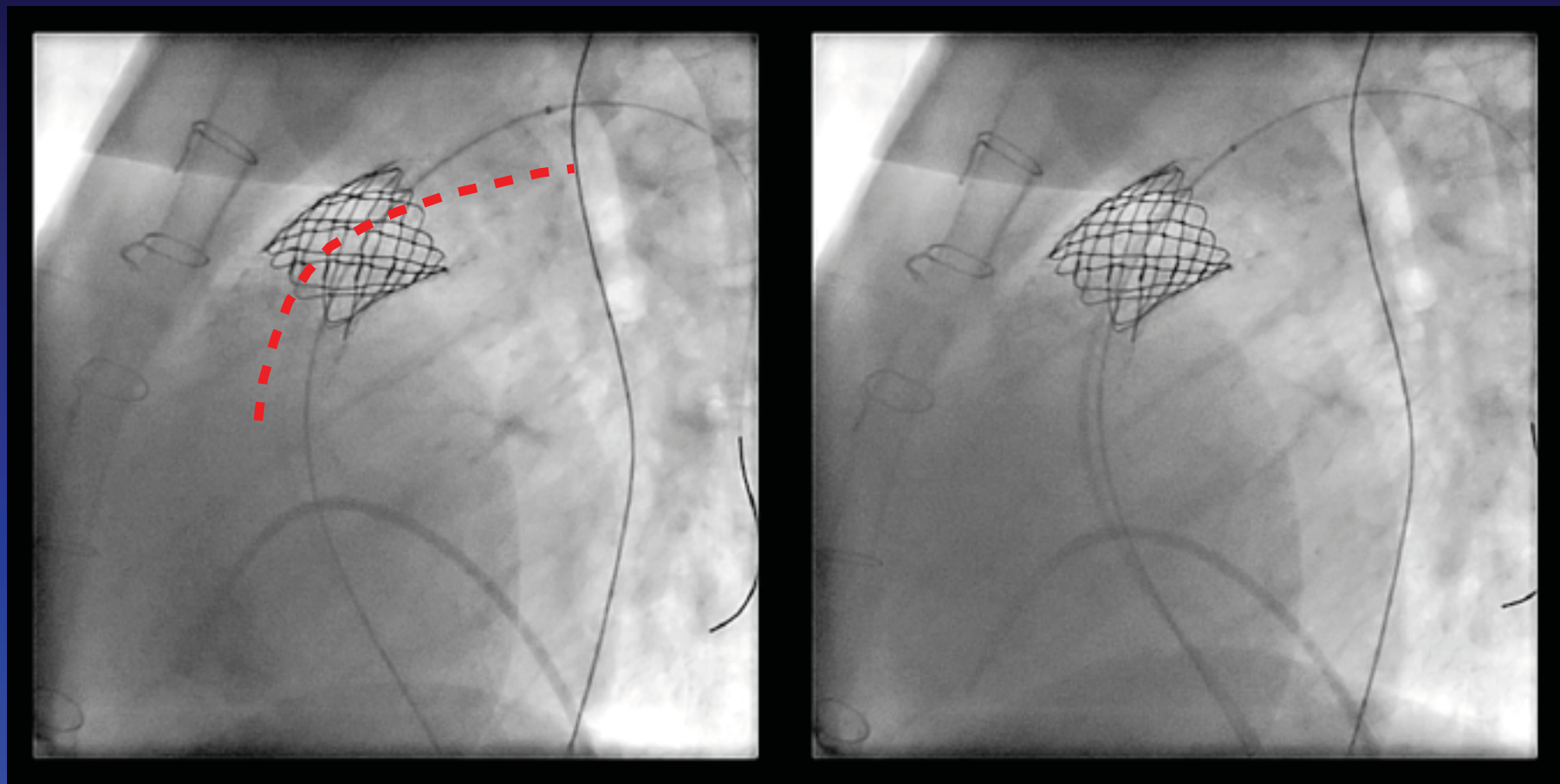
Implanting 2nd Maxi-LD stent



Implanting Melody valve



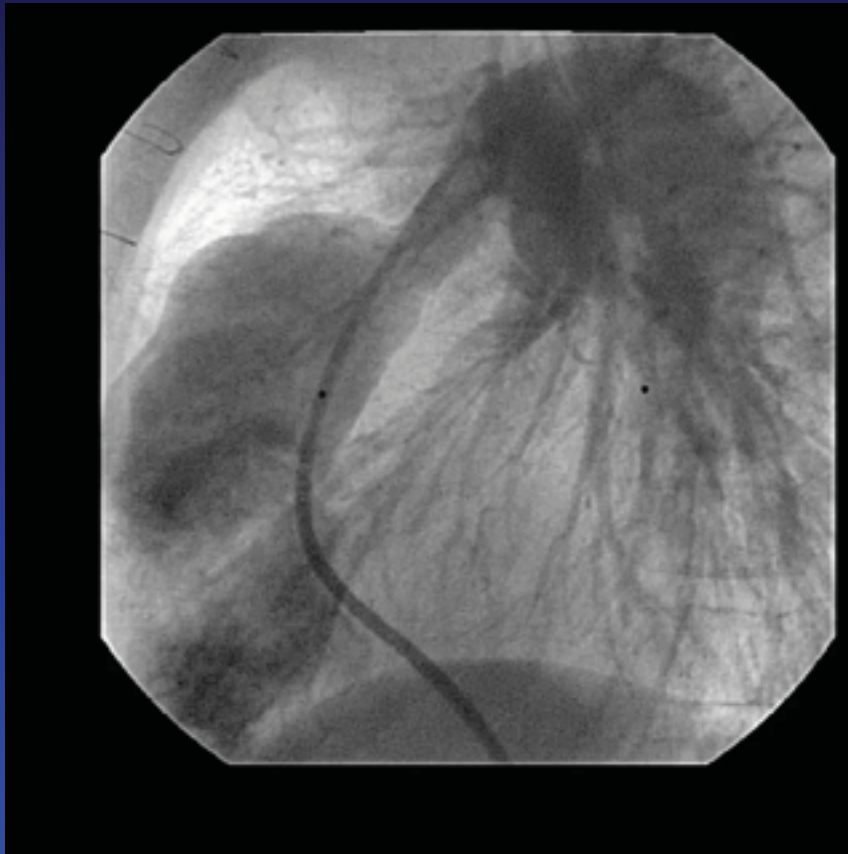
Post Melody angiograms



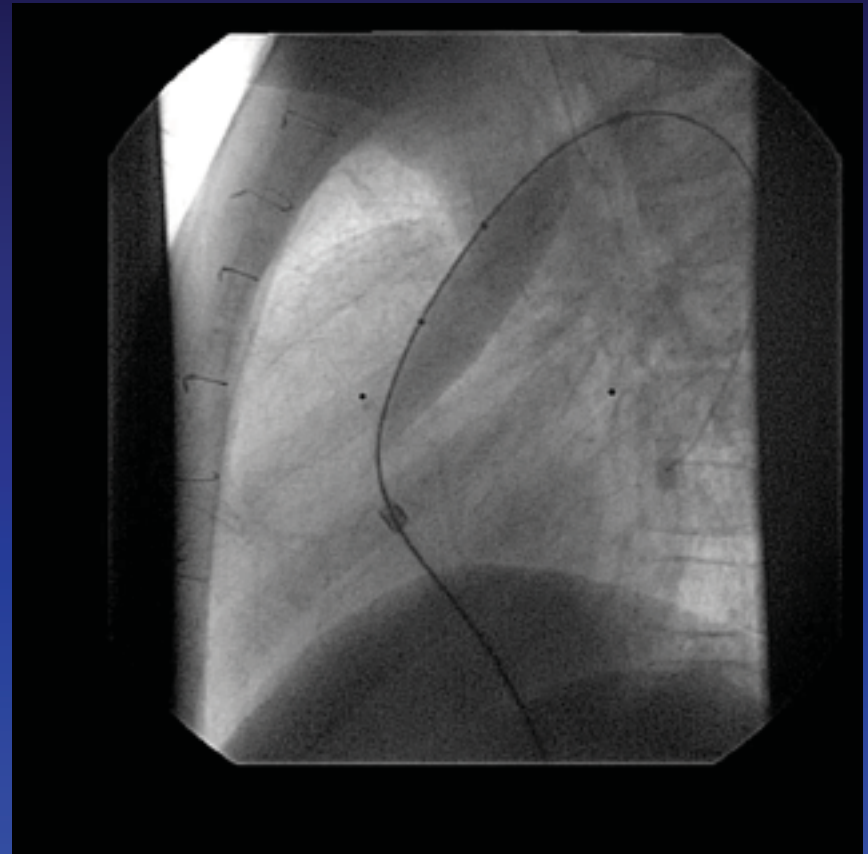
- FDA approval for use in conduits 16-22mm diameters
- Some pulmonary homografts and Contegra valves have ability to dilate and expand larger than original size
- 24mm size conduit
 - 24mm BIB
 - Hybrid implants

12 mm pulmonary homograft

Diameter 9.6 mm

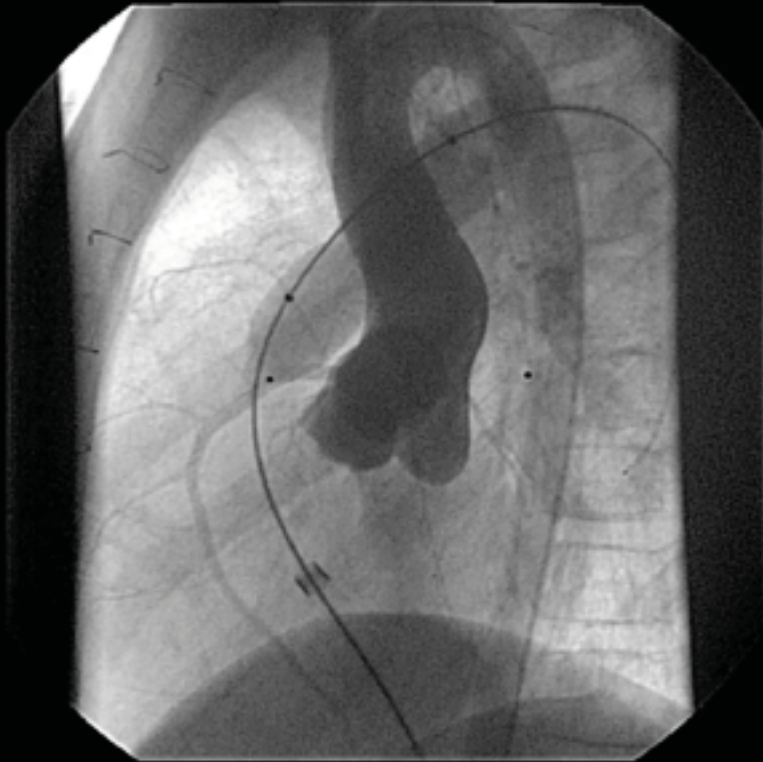


Angioplasty with 12 mm balloon

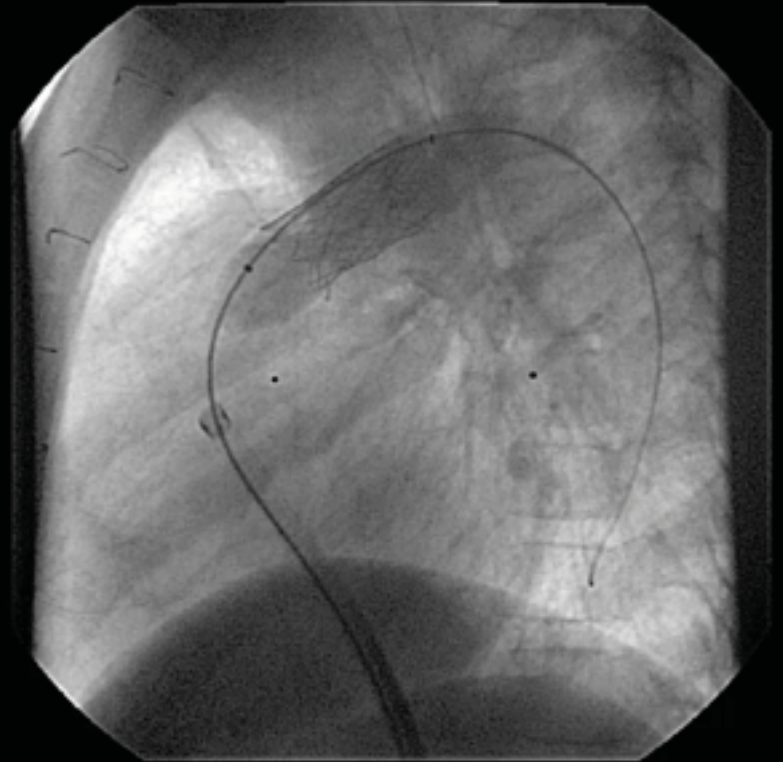


Initial stent implant

Angioplasty with 14 mm balloon



Stent implant with 14 mm balloon

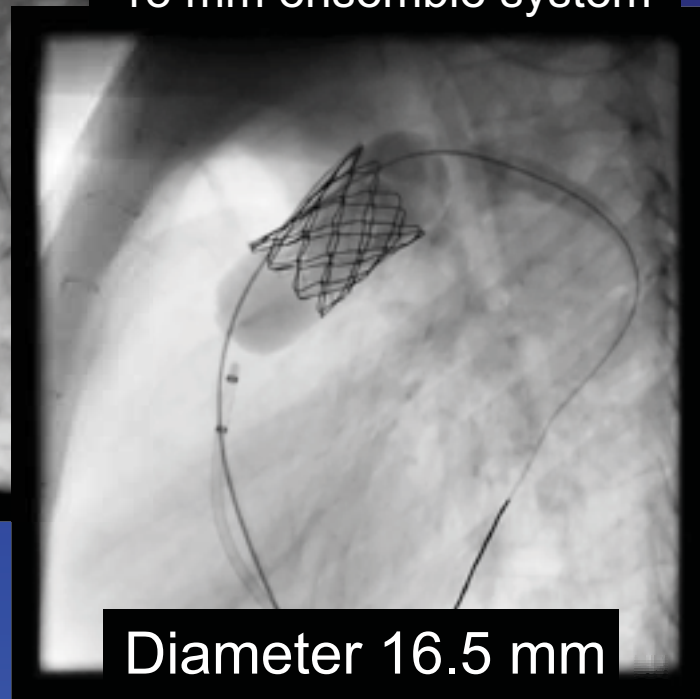


F/U cath 21 months later

Angioplasty with 18 mm balloon



Implant Melody valve with
18 mm ensemble system



Diameter 16.5 mm

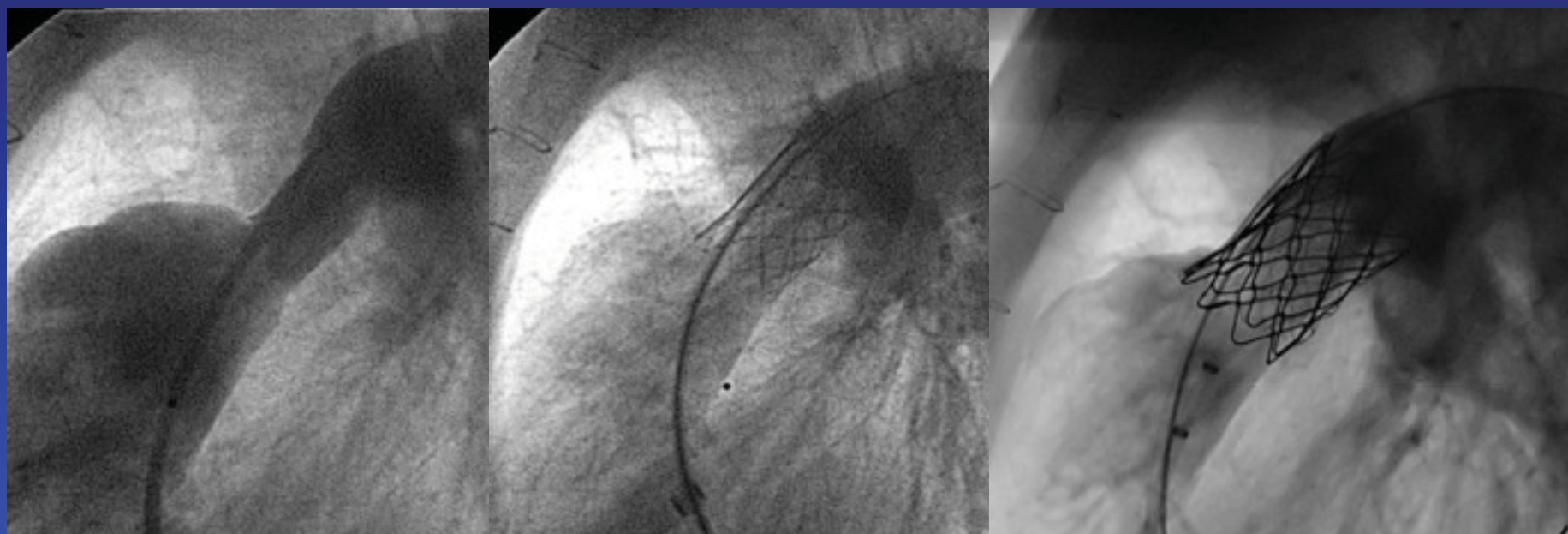
12 mm pulmonary homograft over-expanded with Melody on 18 mm ensemble system

Lat

Pre
9.6 mm

S/P 16mm stent
15.5 mm

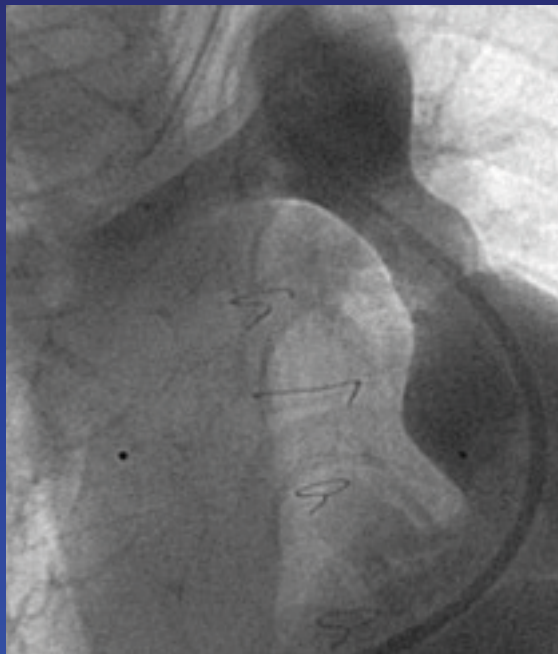
S/P 18mm Melody
16.5 mm



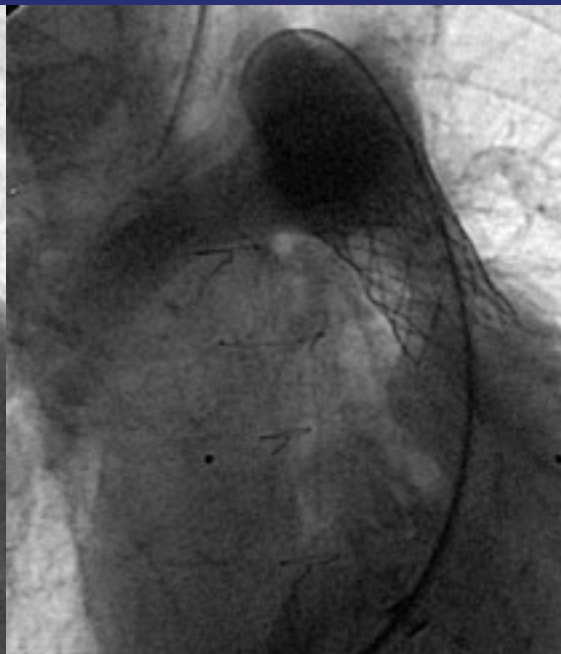
12 mm pulmonary homograft over-expanded with Melody on 18 mm ensemble system

AP

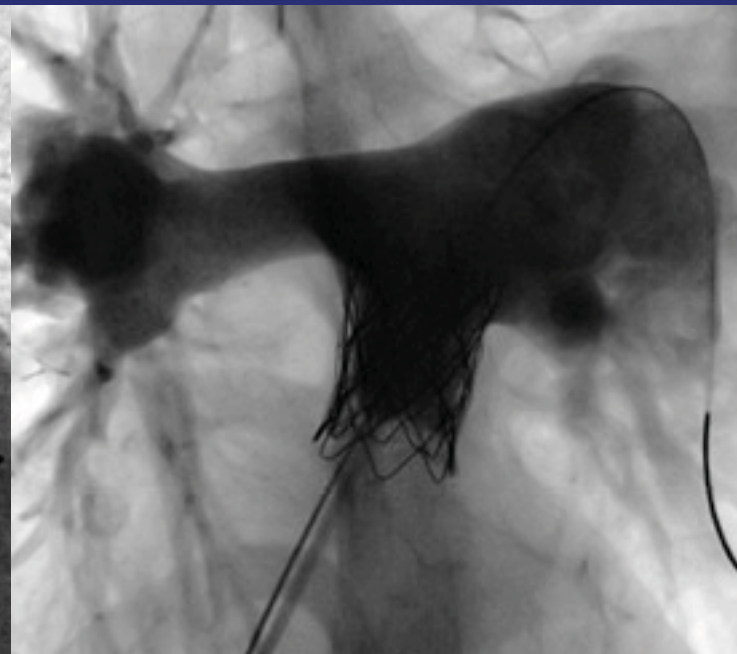
Pre



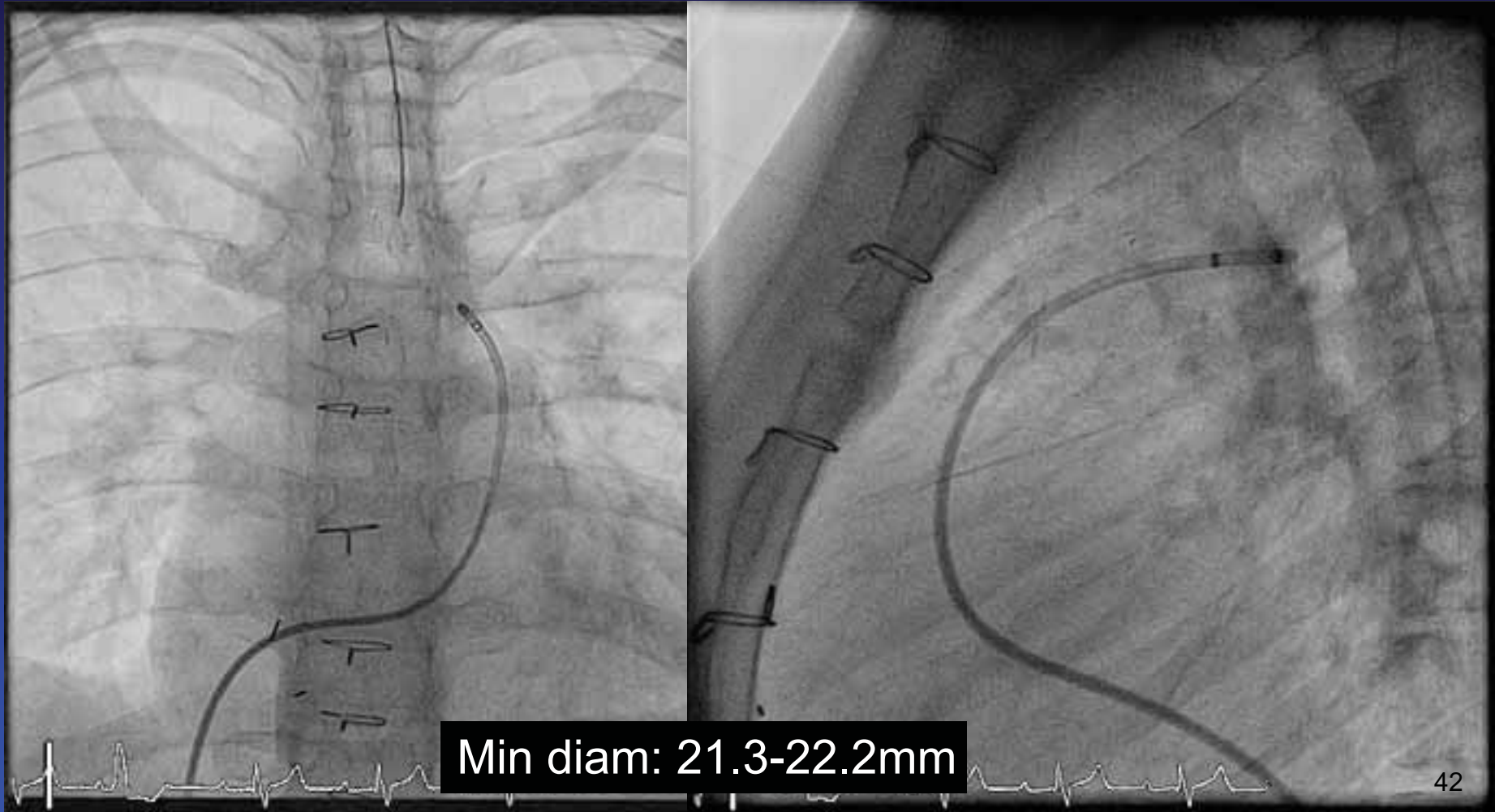
S/P 16mm stent



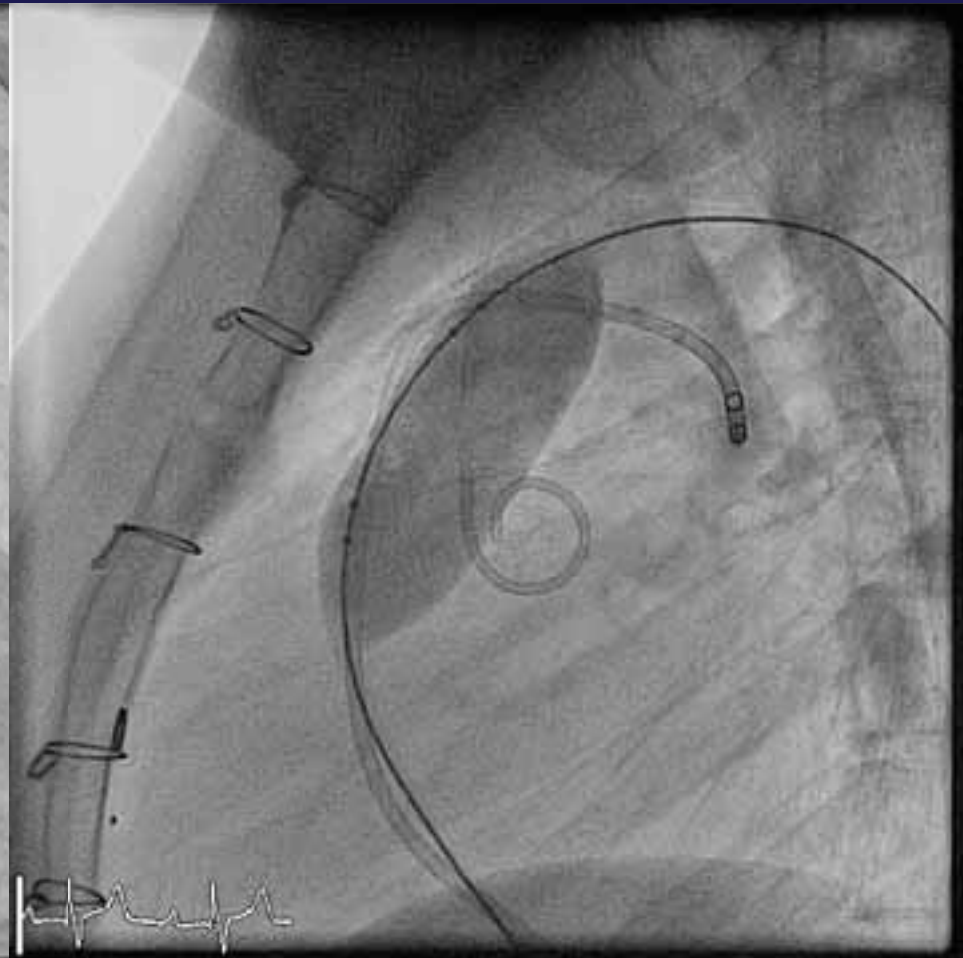
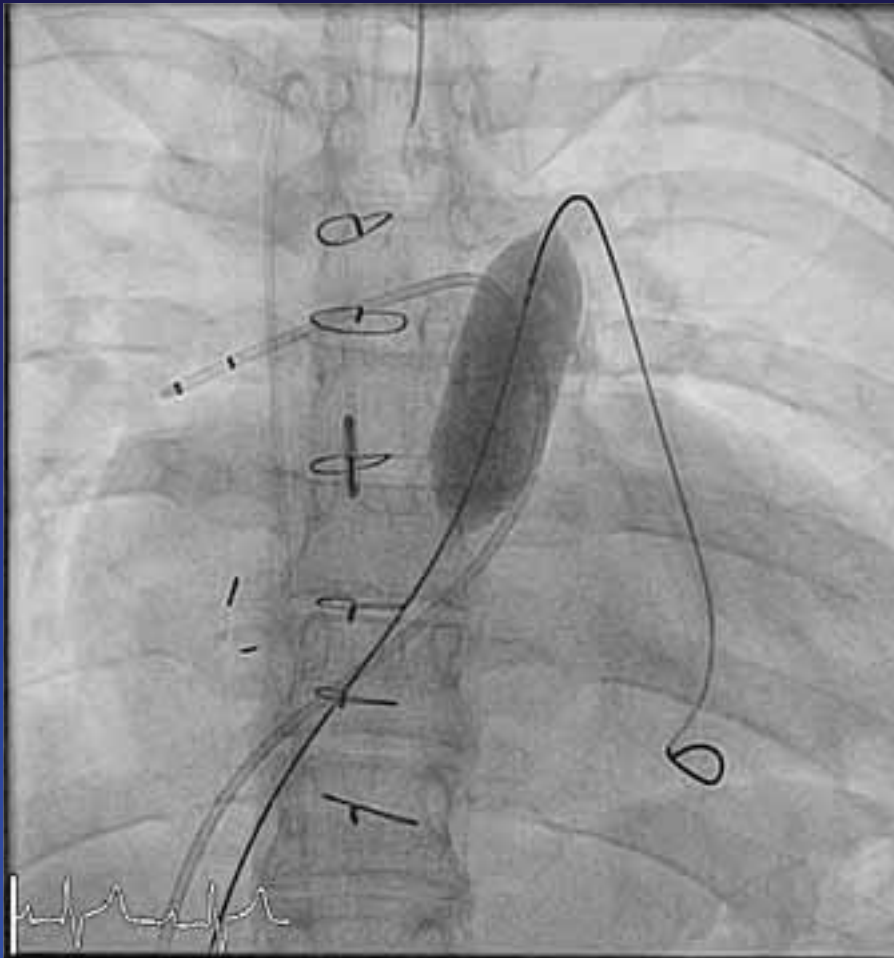
S/P 18mm Melody



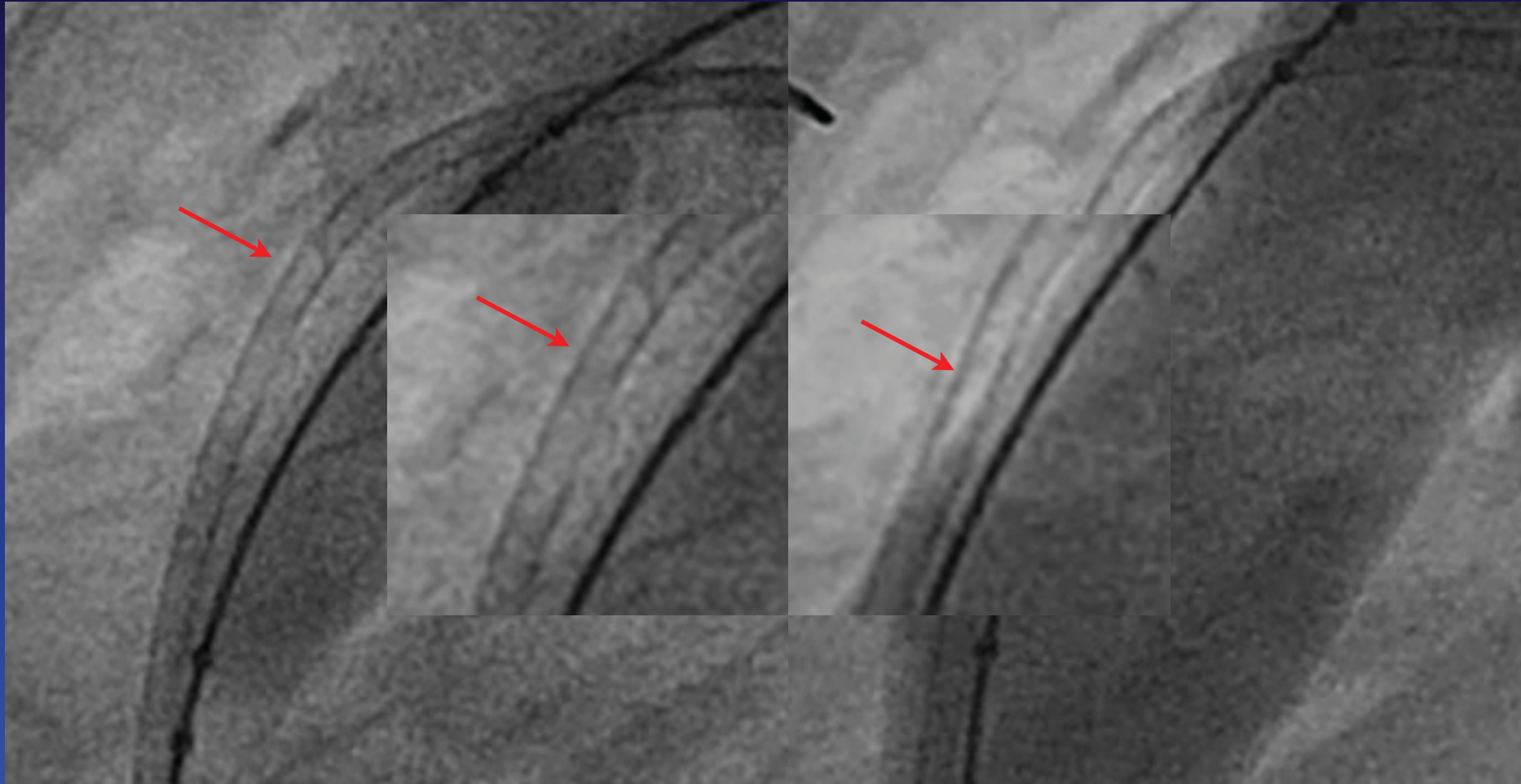
19 yo F s/p 24 mm Rv-PA conduit



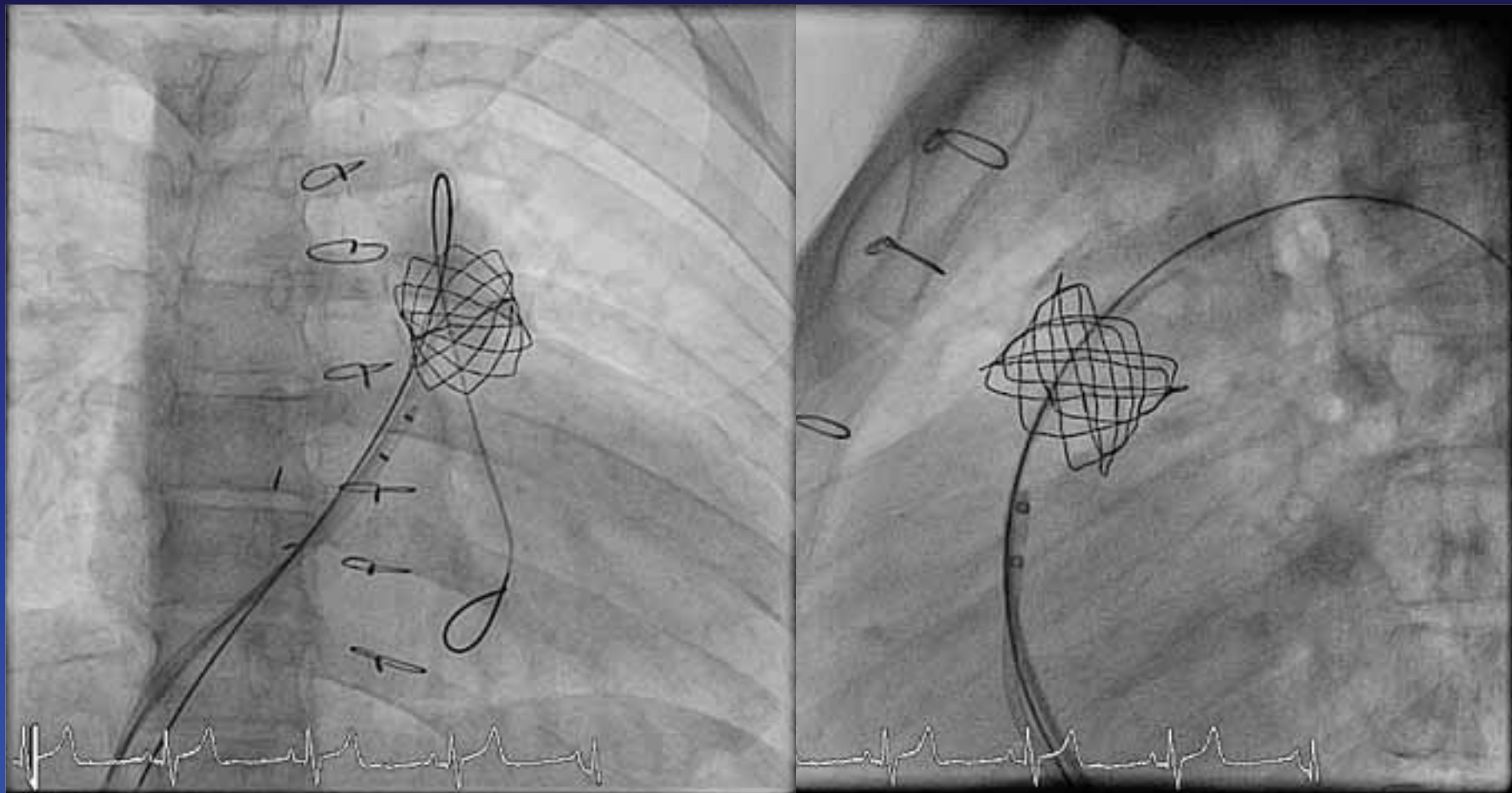
Testing with 22mm balloon No waist



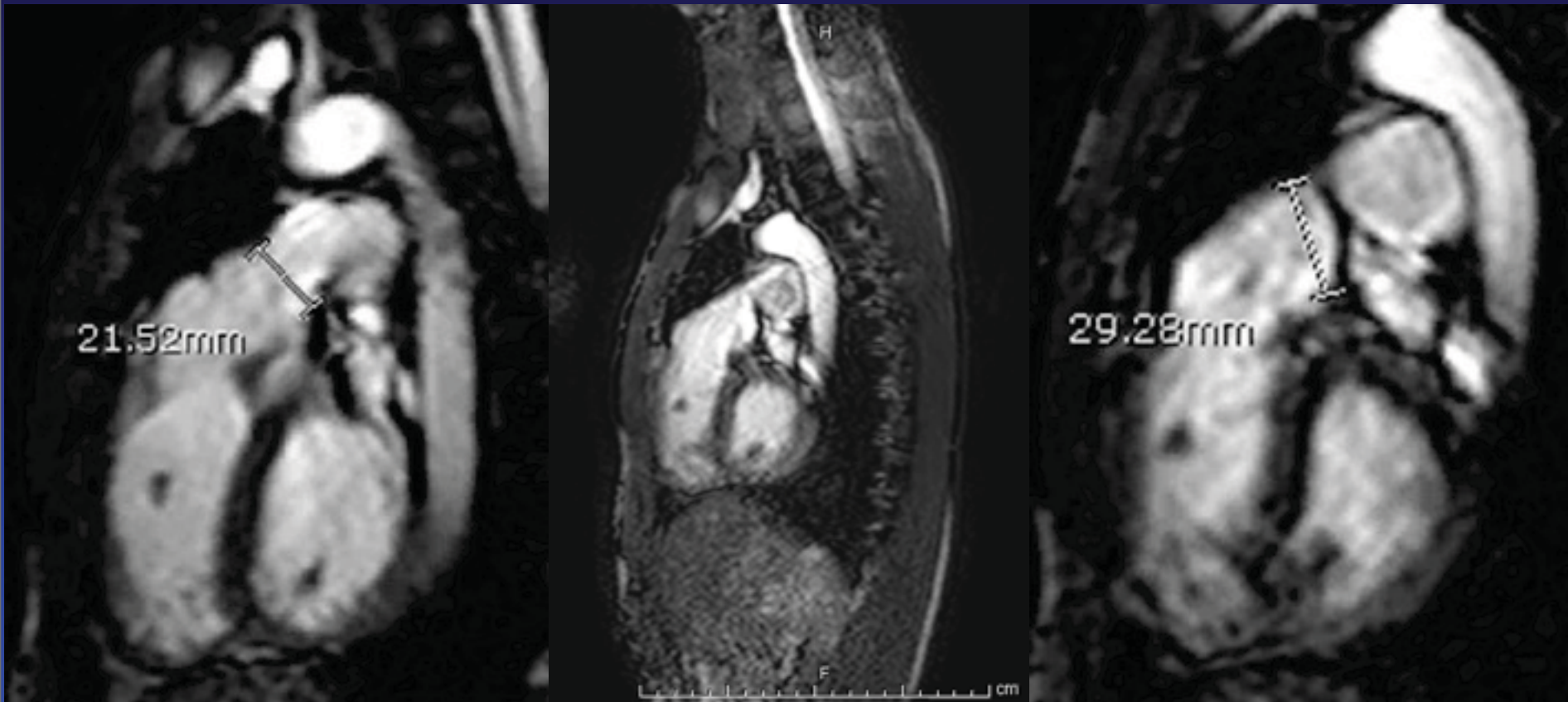
Testing with 24mm balloon: Subtle waist (see compressed catheter)



Melody implant on 24 mm BIB

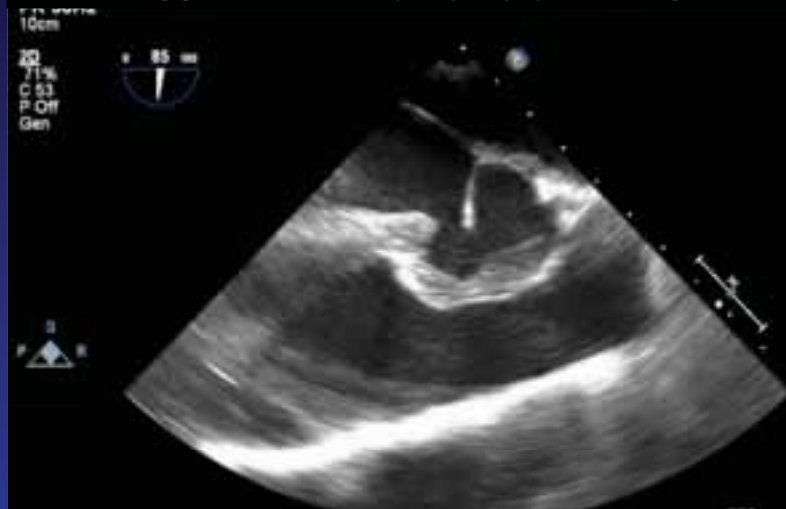


TOF, S/P transannular patch with PI and dilated RVOT

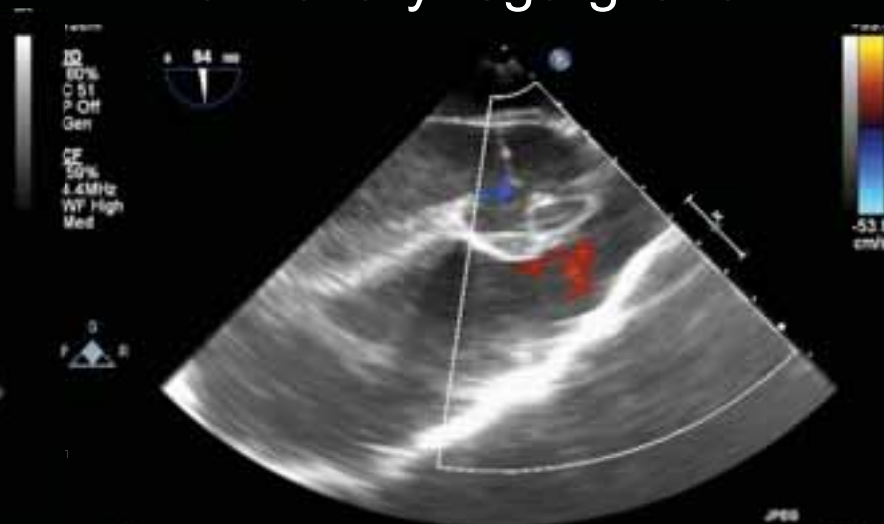


Hybrid Melody implant: PA band to anchor Melody valve

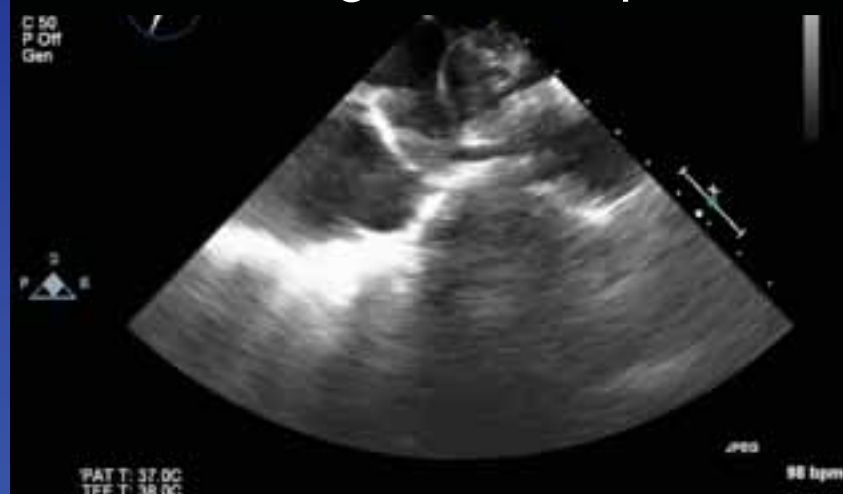
S/P TAP-dilated RVOT



Pulmonary regurgitation



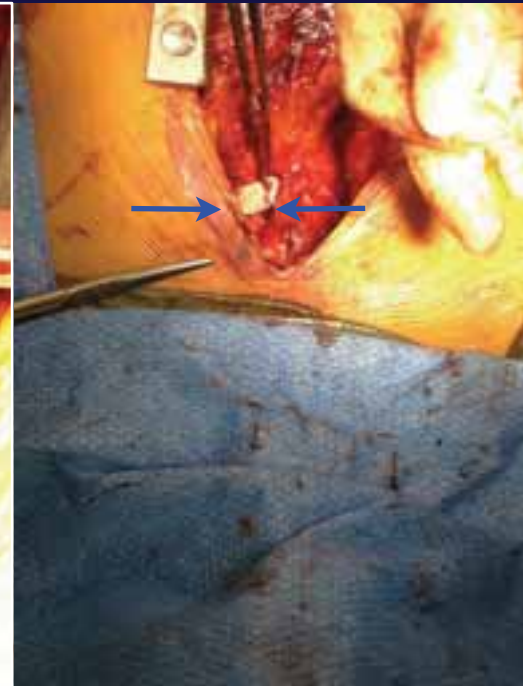
Determining PA band position



Preparing the MPA band

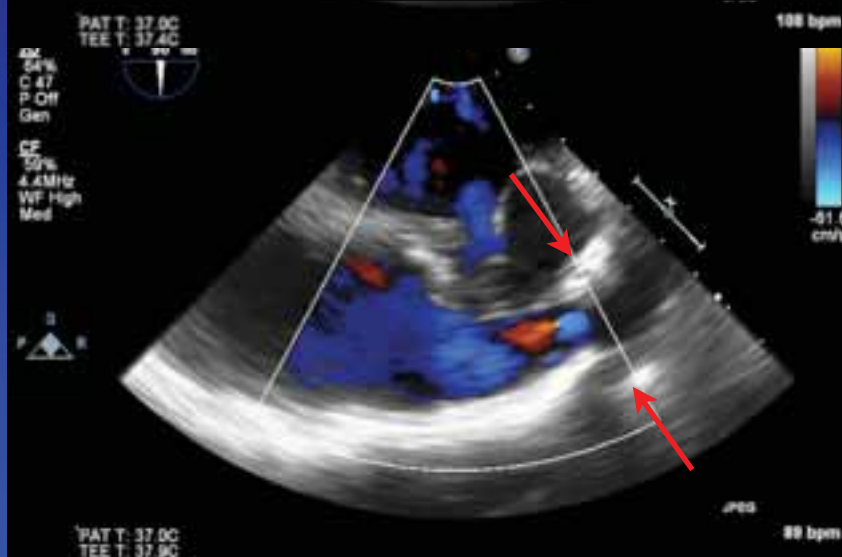
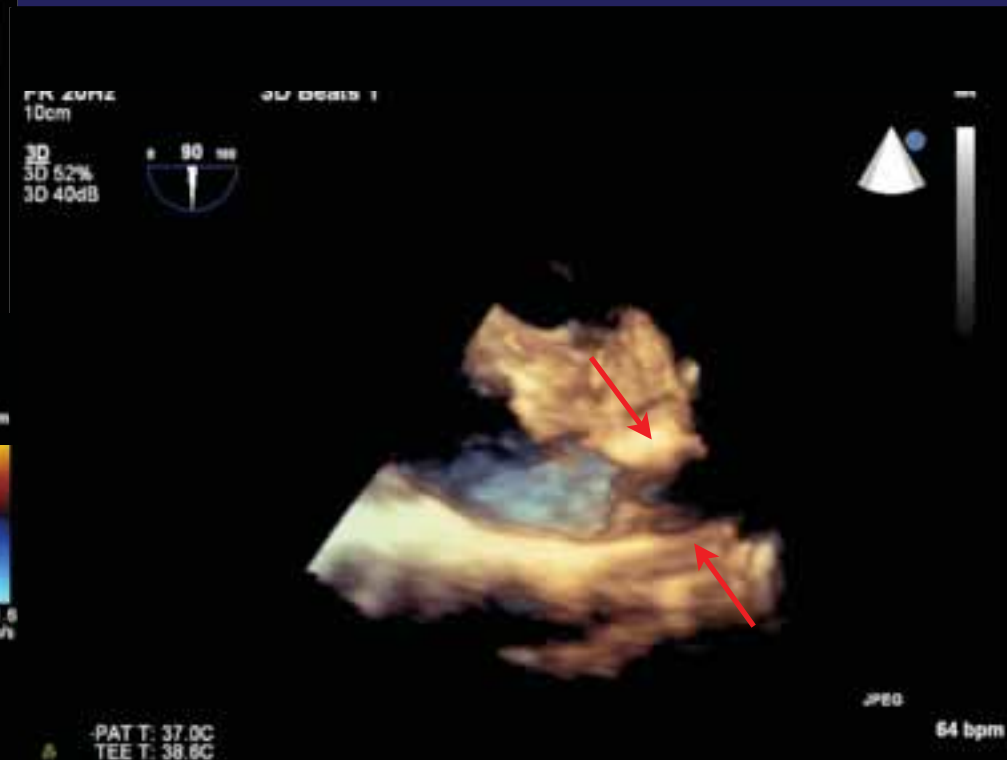
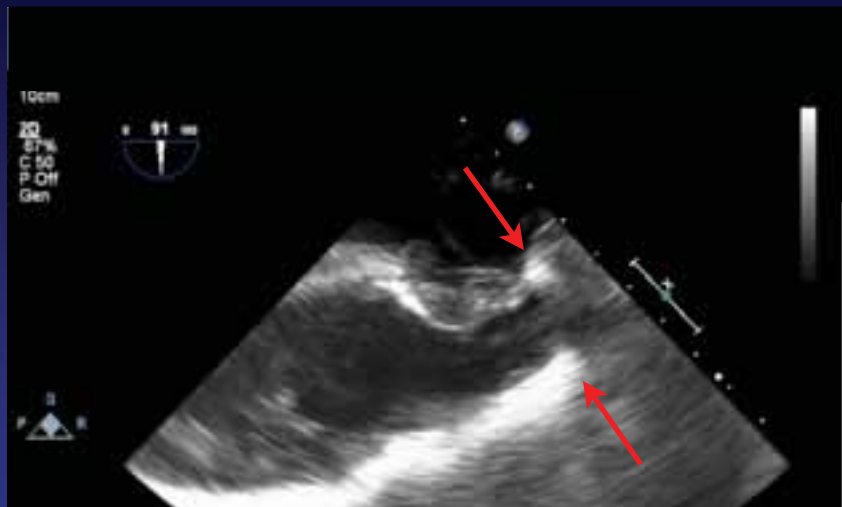


22 mm Gortex tube-

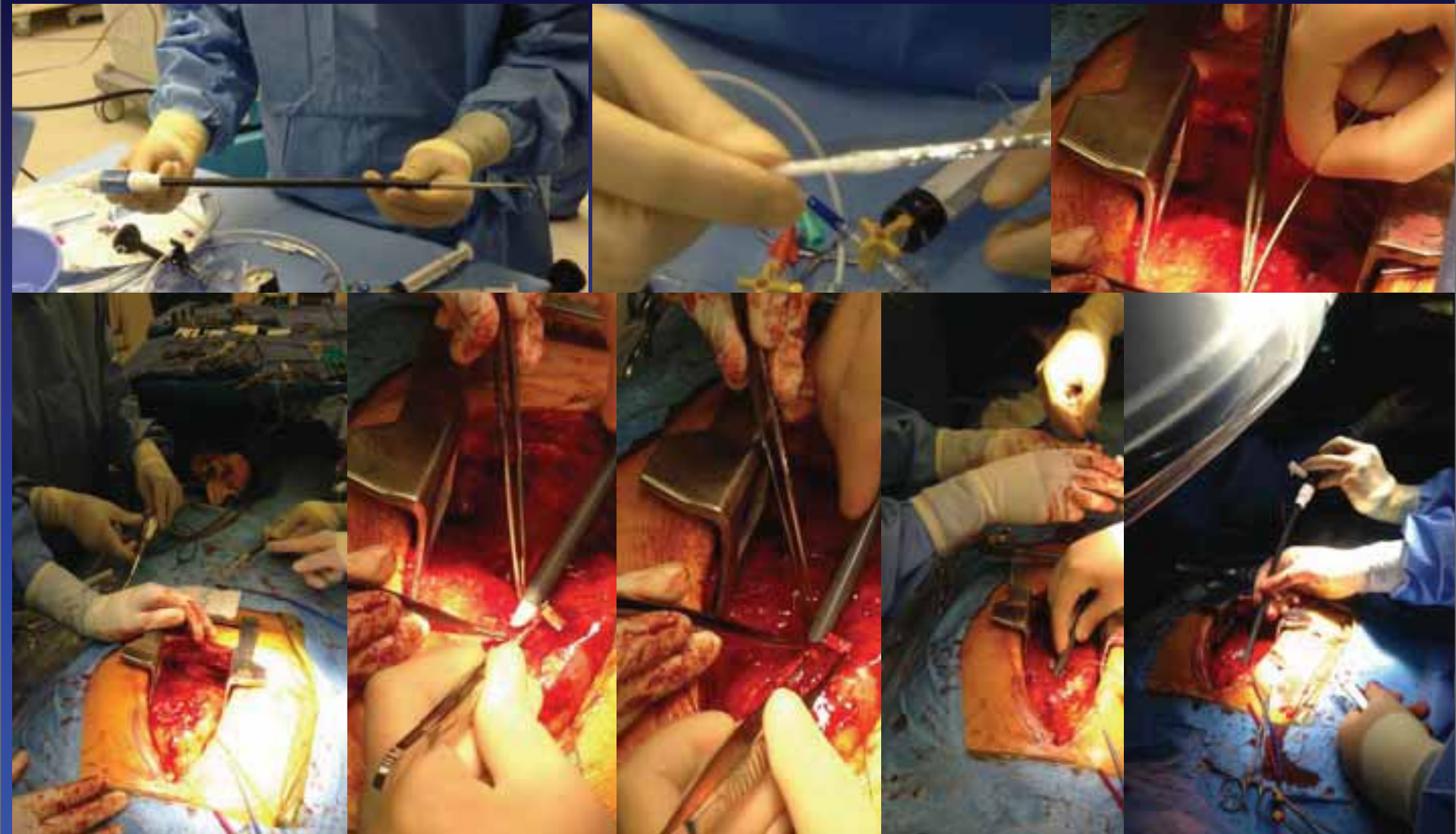


Place around MPA
(must avoid LCA)

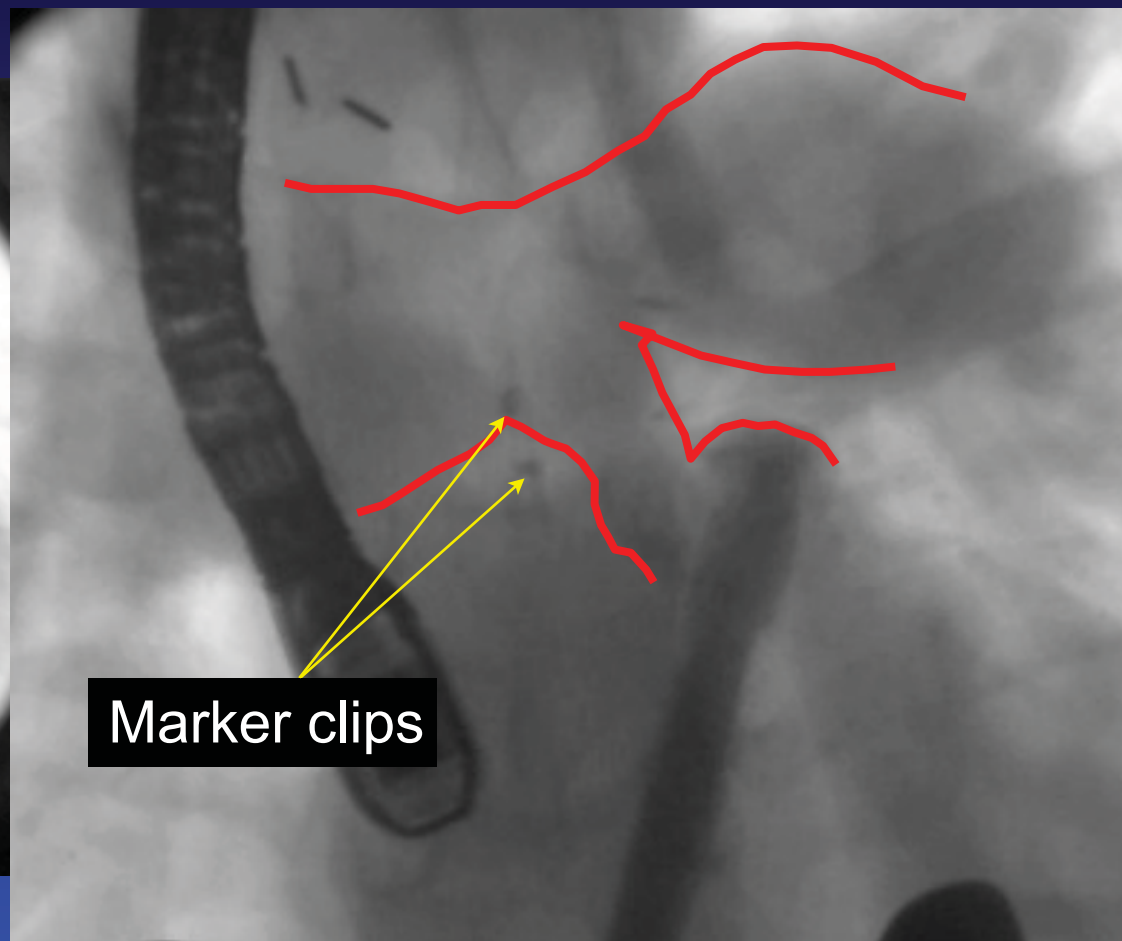
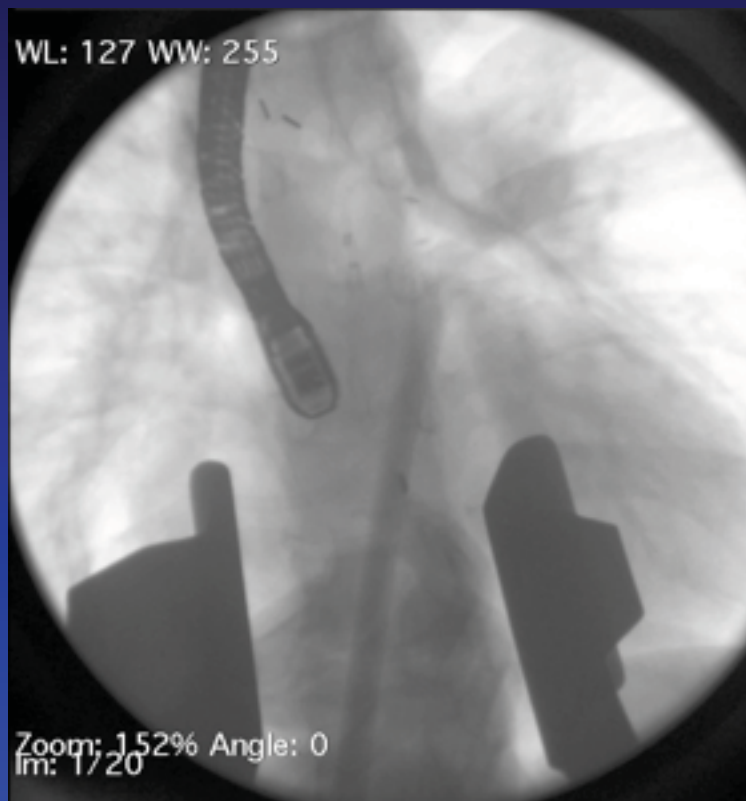
S/P MPA band



Preparing 22 fr sheath and 4110 Palmaz stent on 24 mm BIB



Flouroscopy guidance: 22 Fr sheath in RVOT



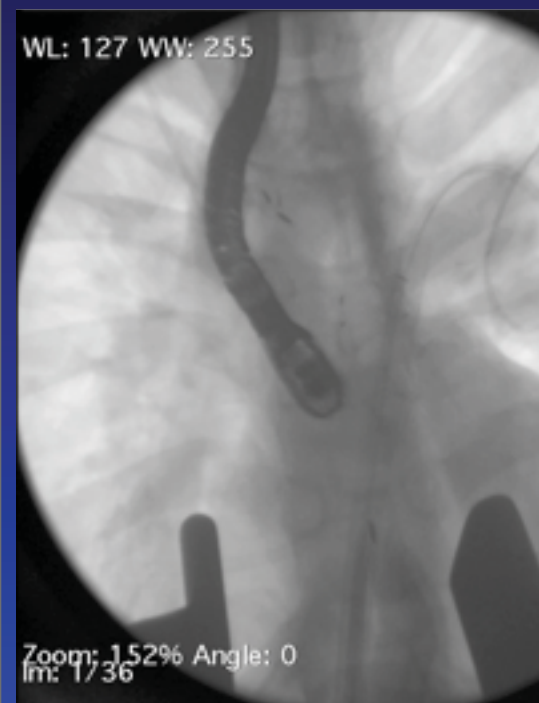
Implanting 4010XL stent at banded site



Wire-stent-balloon across PA band

Balloon inflation/stent implantation

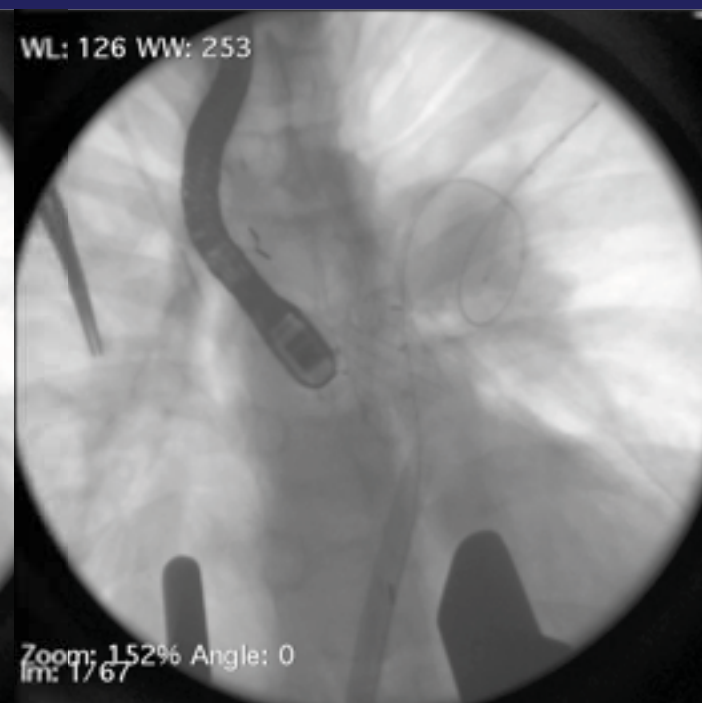
Flouroscopy: Implantation of Palmaz 4110 XL stent on 24 mm BIB



Advancing stent



Implanting stent



Post stent angio

Stent implantation in RVOT

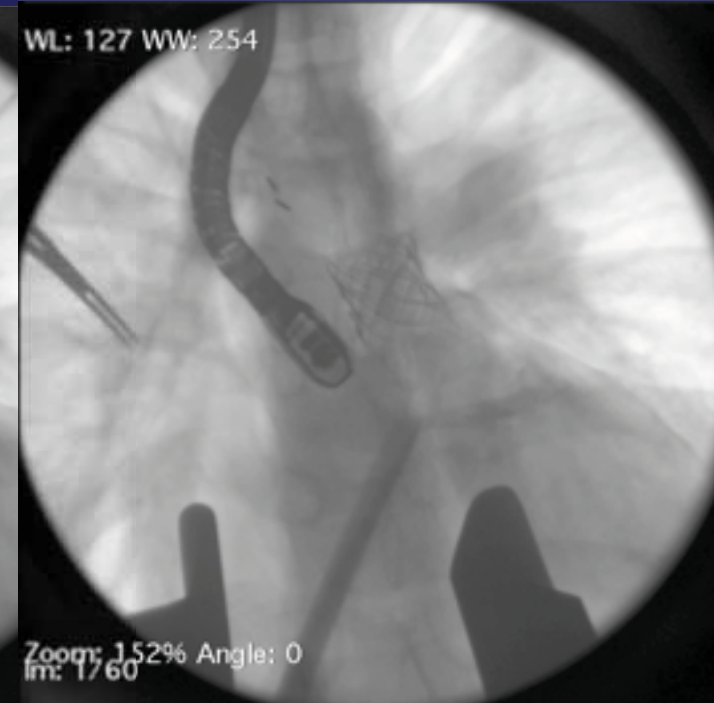
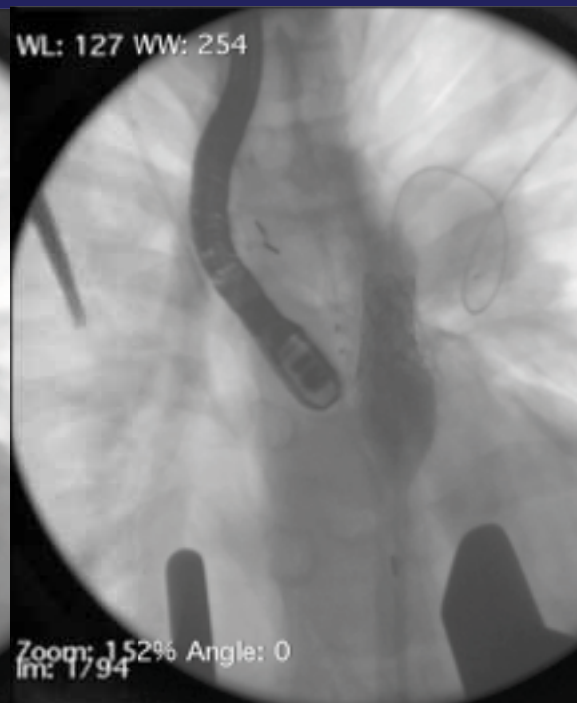
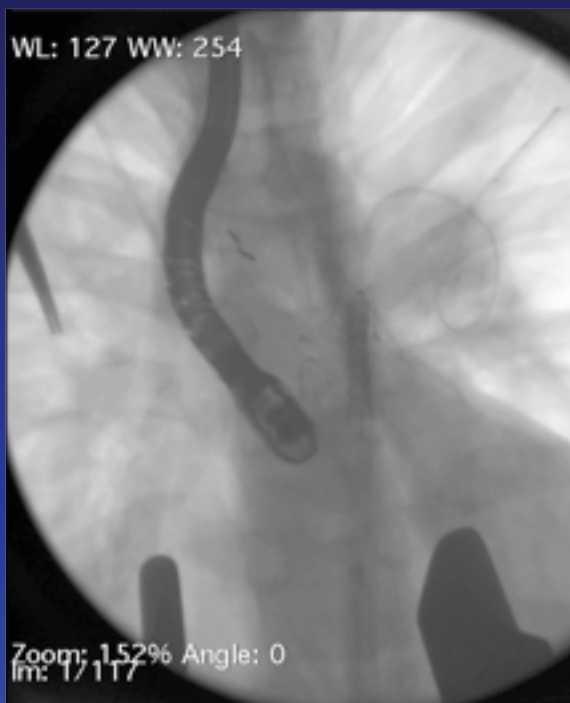


Melody valve mounted on 24 mm BIB



24 mm BIB

Implantation of Melody valve on 24 mm BIB



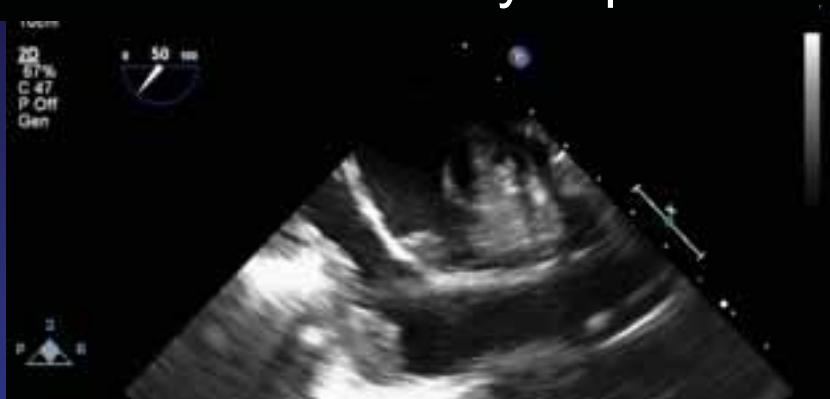
Advancing Melody

Implanting Melody

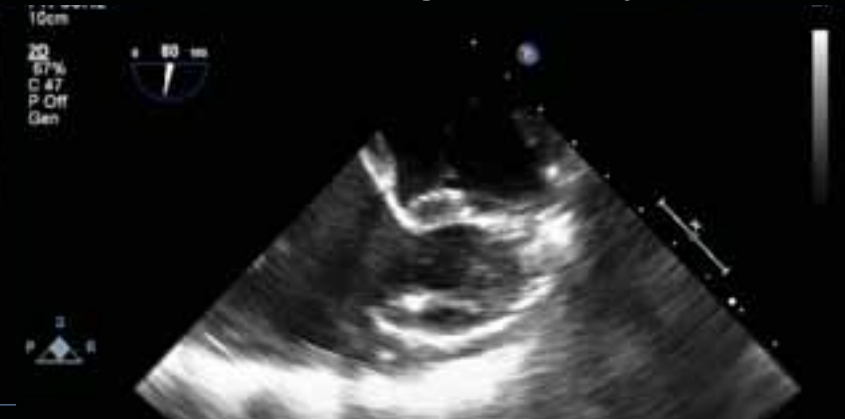
Post Melody angio

Intraop TEE

Balloon and Melody in position



Implanting Melody



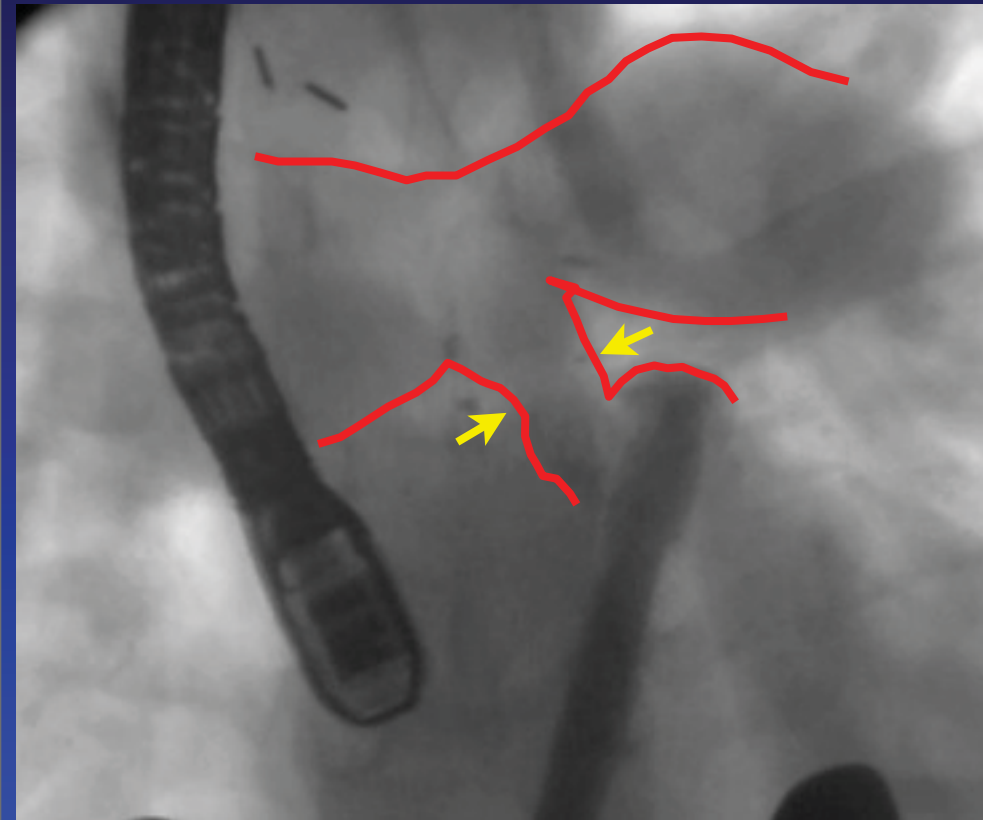
Melody implanted



Post TEE



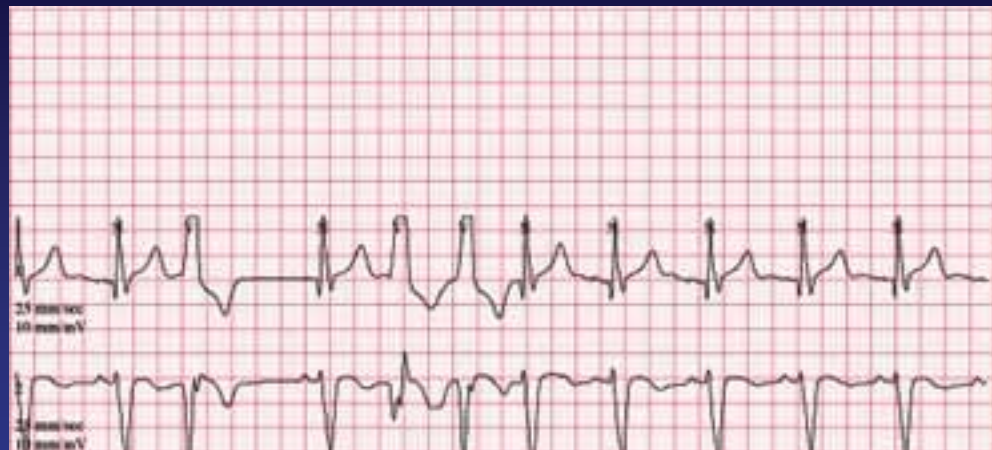
Pre and post angiogram



MPA band

- Beware of coronary artery compression
- Melody valve stent fracture
 - Pre-stenting prior to Melody valve implant
- Conduit issues:
 - Calcified conduits; dissections and ruptures
 - Angulated conduits
 - Extending limits of homografts
- Venous/IJ access issues
- “Figure of 8” stitch for venous hemostasis
- **Post Melody implant**
 - **Arrhythmias**
 - **Endocarditis issues**
- Melody valve implant in other positions

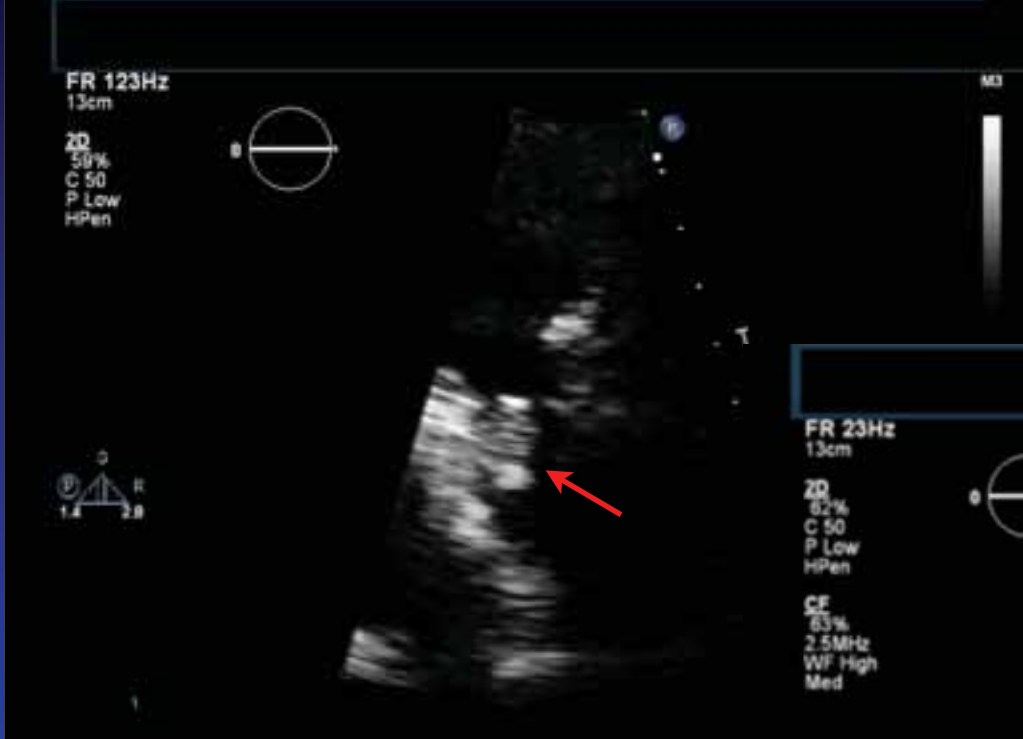
Post Melody implant arrhythmias



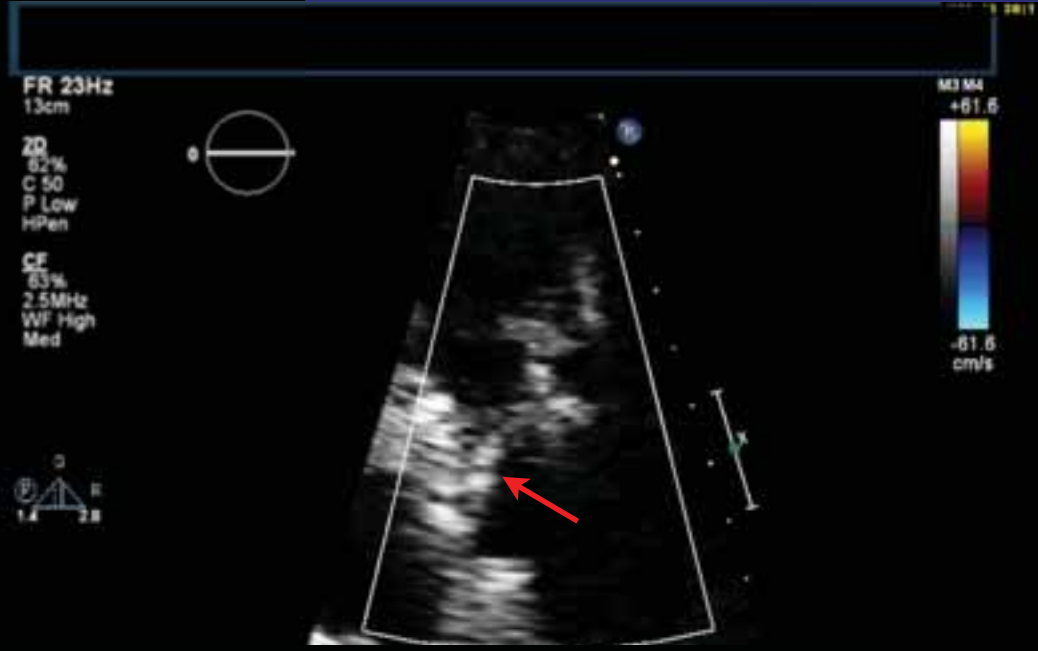
Treat with beta-blockers for 6 months,
then discontinue and re-holter



Post Melody valve implant: fever and bacteremia-diagnosis?



- Positive blood culture
- Dental flora



- Dental clearance before any device implant

129 bpm

Path specimen



- No standards for antibiotics coverage
- Pre-implant dental clearance; repair all cavities
- Pre-implant antibiotics x 1
- Change gloves when handling new Melody valve
- Lifetime SBE prophylaxis
- Medtronic- >5000 cases
 - 93 cases reported to them (1.9% incidence)

Summary

- The Melody valve is a safe and effective palliative device to augment the lifespan of a RV-PA conduit
- Many potential problems encountered before, during and after procedure that needs subtle algorithms to ensure safety and efficacy
- Pay attention to little details