

# Transcatheter Mitral Valve Implantation

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# CardiAQ™ TMVR System

## Multiple access routes

- Transfemoral      successful FIH June 2012
- Transapical      successful FIH May 2014

## Controlled deployment

- Multi-stage deployment

## Accurate positioning

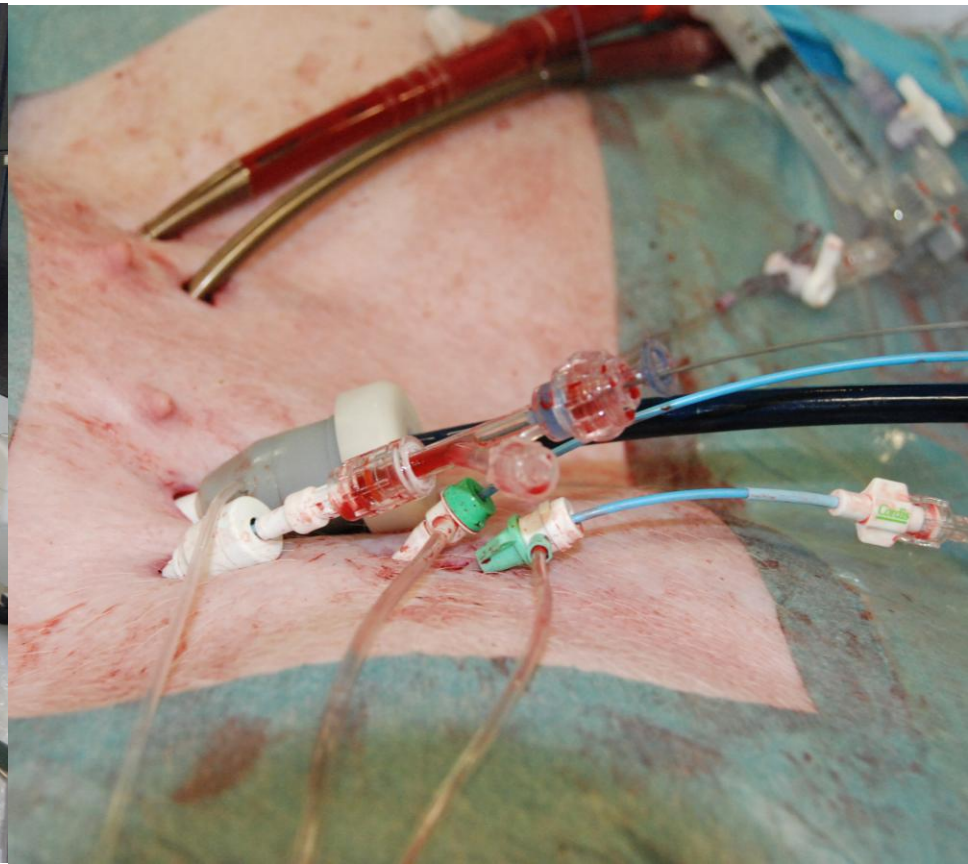
- Self-positioning within native valve annulus
- Intra/supra annular placement to preserve LV contractility and maximize LVOT area

## Secure anchoring

- Preserves native chordae and leaflets
- Anchoring without radial force



# Animal studies



# Clinical results

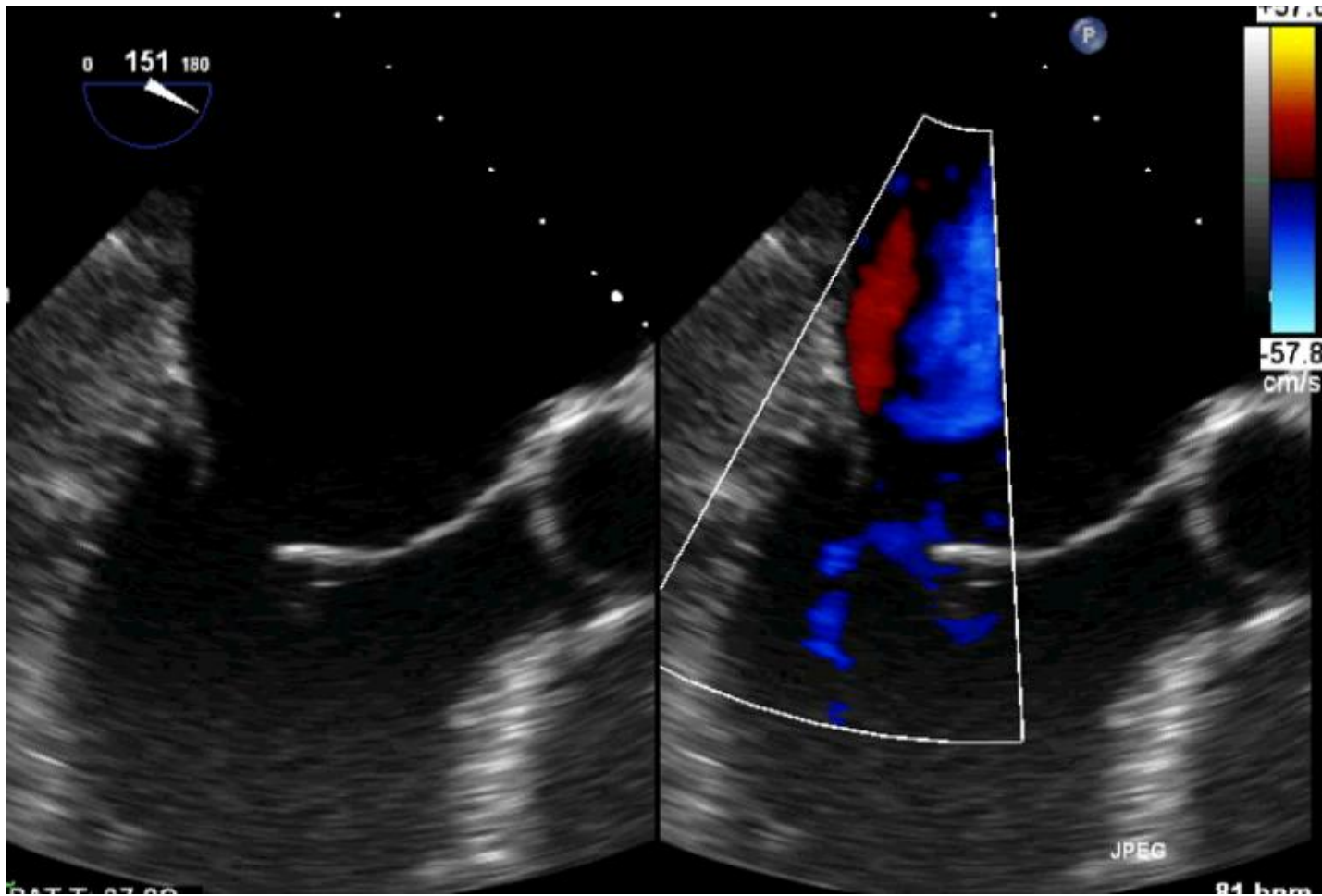
## *4 patients treated in Copenhagen:*

- All turned down for surgery and technically not candidates for MitraClip
- TMVR on compassionate ground approved by DMA

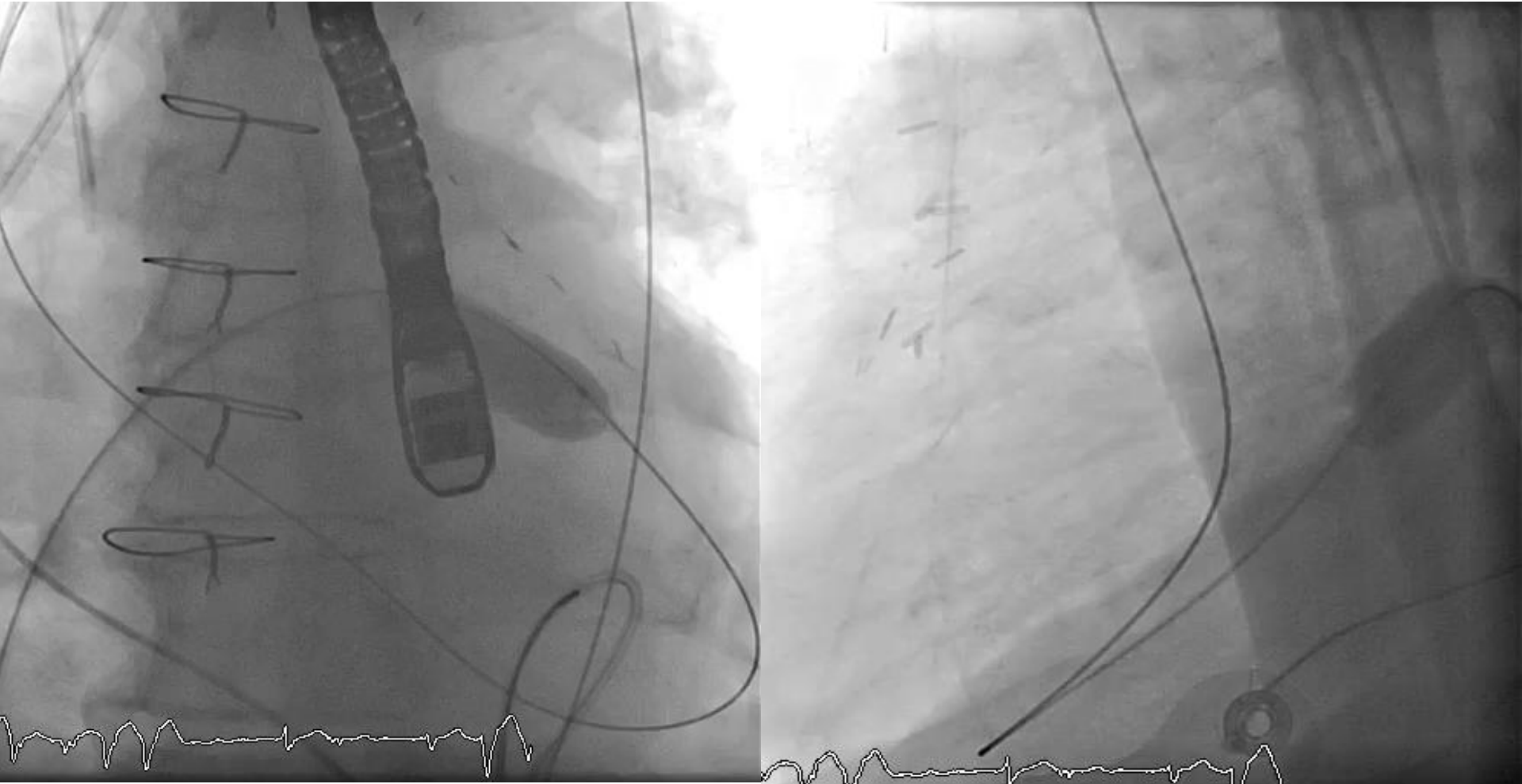
<u>No</u>	<u>Date</u>	<u>Gen</u>	<u>Time</u>	<u>Status</u>		
TF-1	2012/6	1	60 min	Died day	3	(SIRS)
TA-1	2014/5	2	20 min	Alive day	151	
TA-2	2014/7	2	13 min	Alive day	95	
TA-3	2014/7	2	13 min	Died day	9	(pneumonia)



# Annular dilatation & restricted PML



# Copenhagen manoeuvre

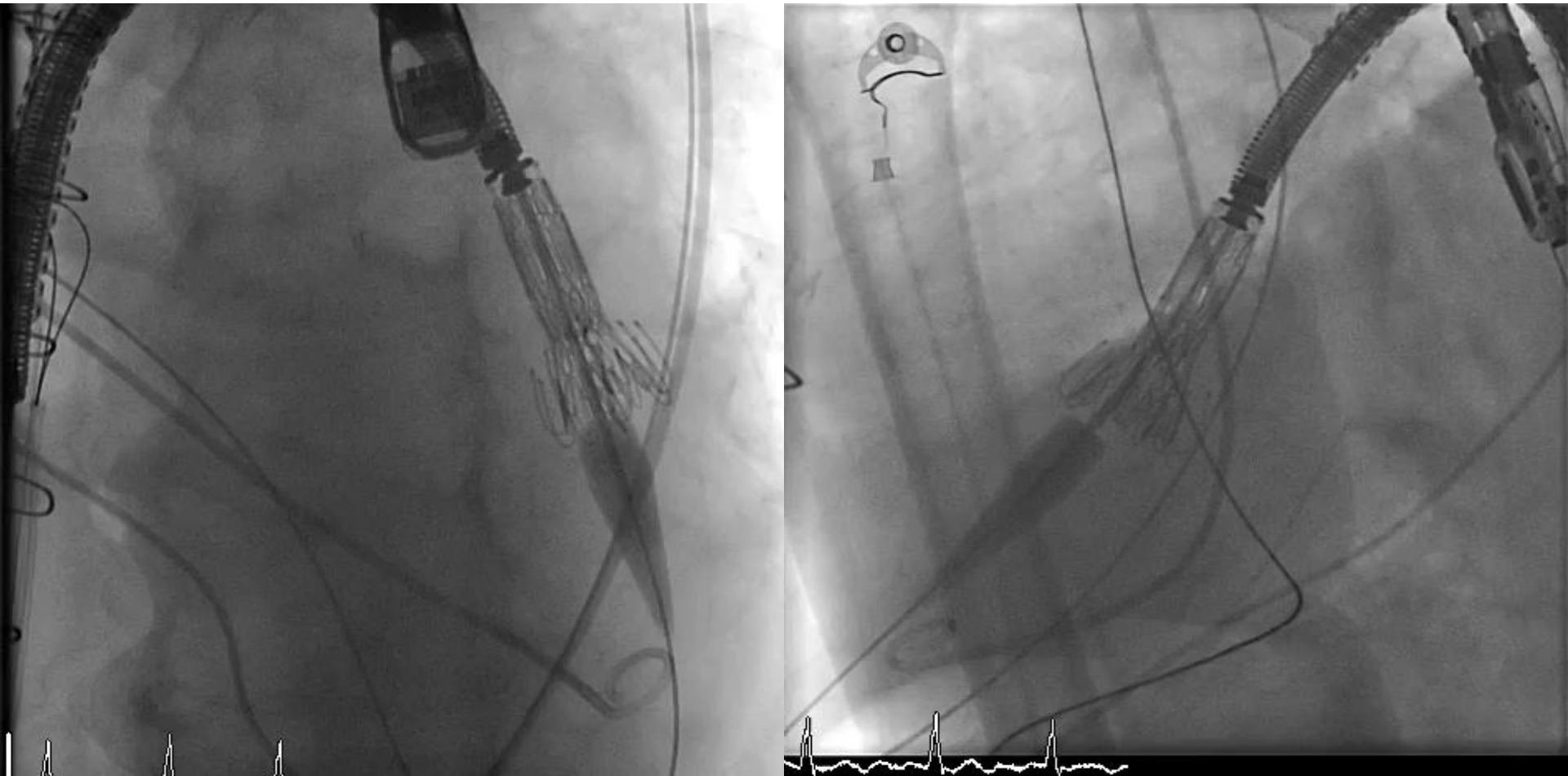


# Coaxial alignment



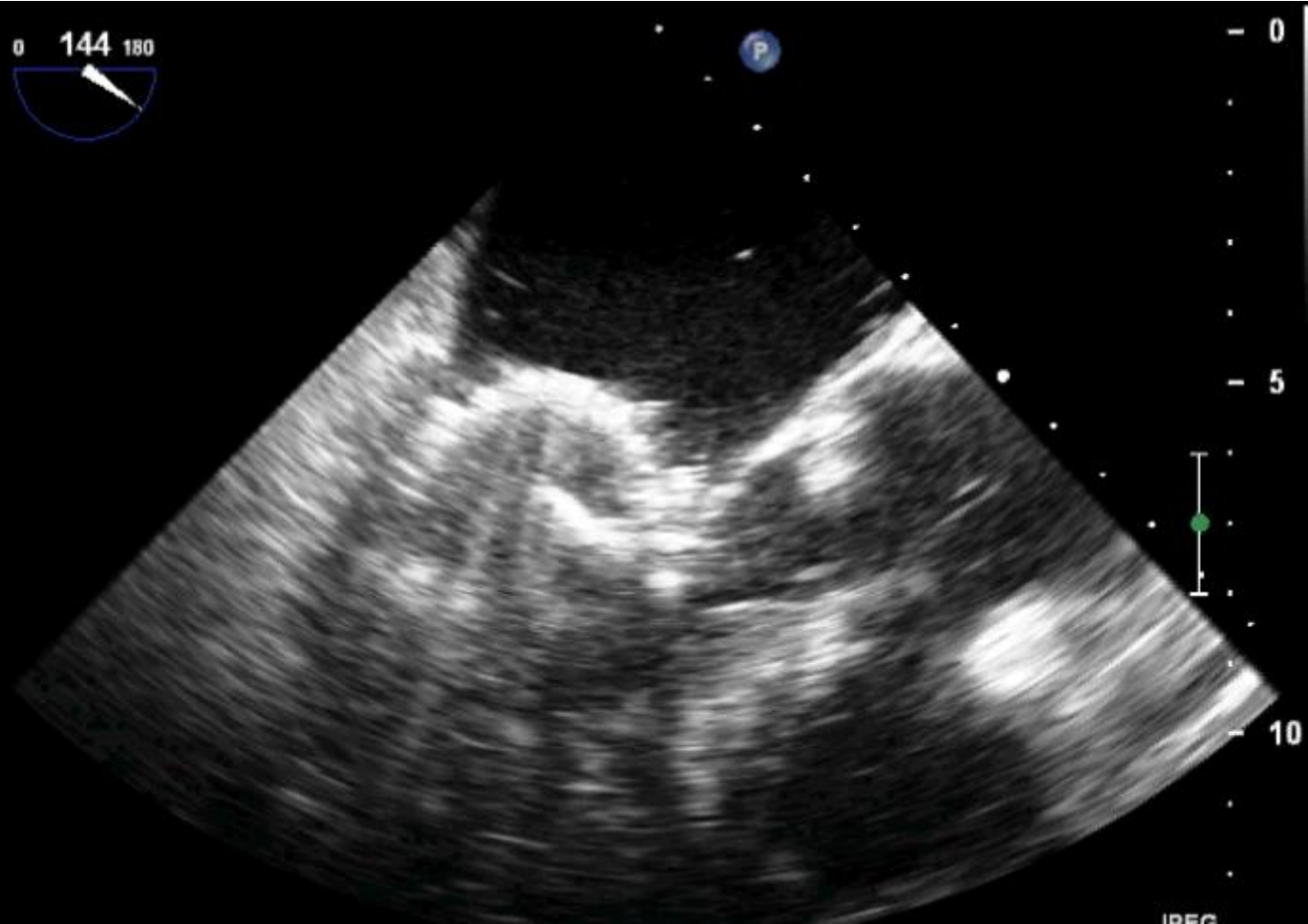


# Opening of ventricular anchors

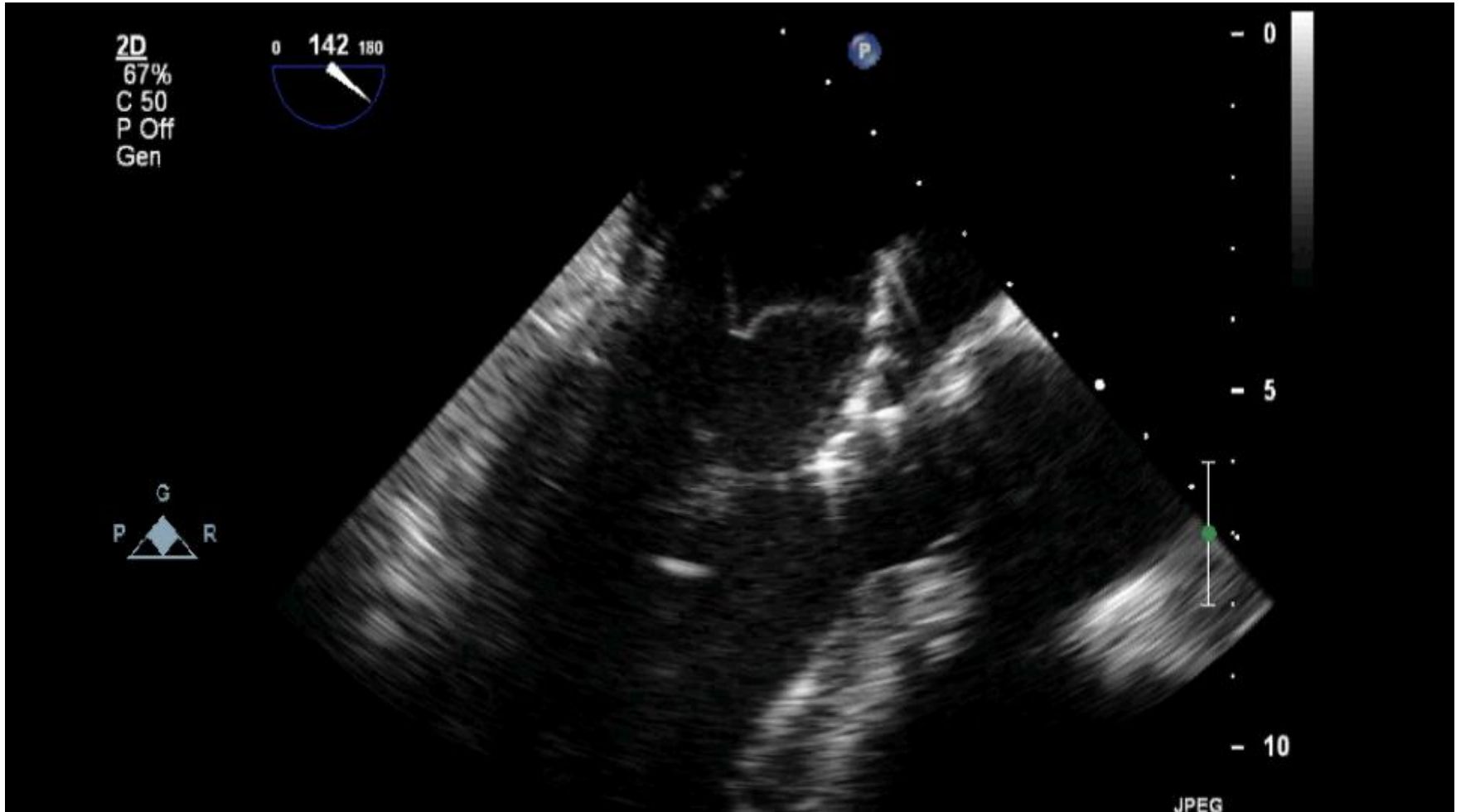


# Secure capture of leaflets

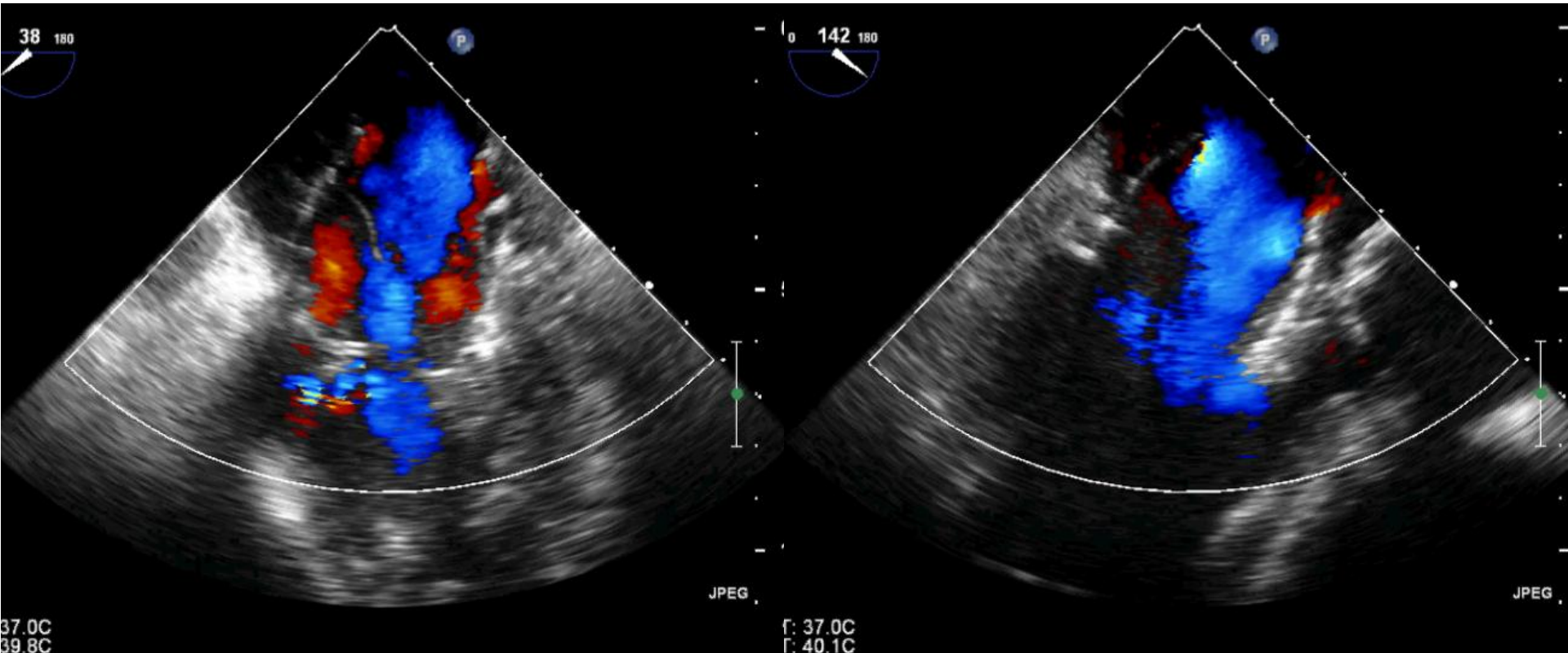
2D  
75%  
C 50  
P Off  
Gen



# Deployed valve

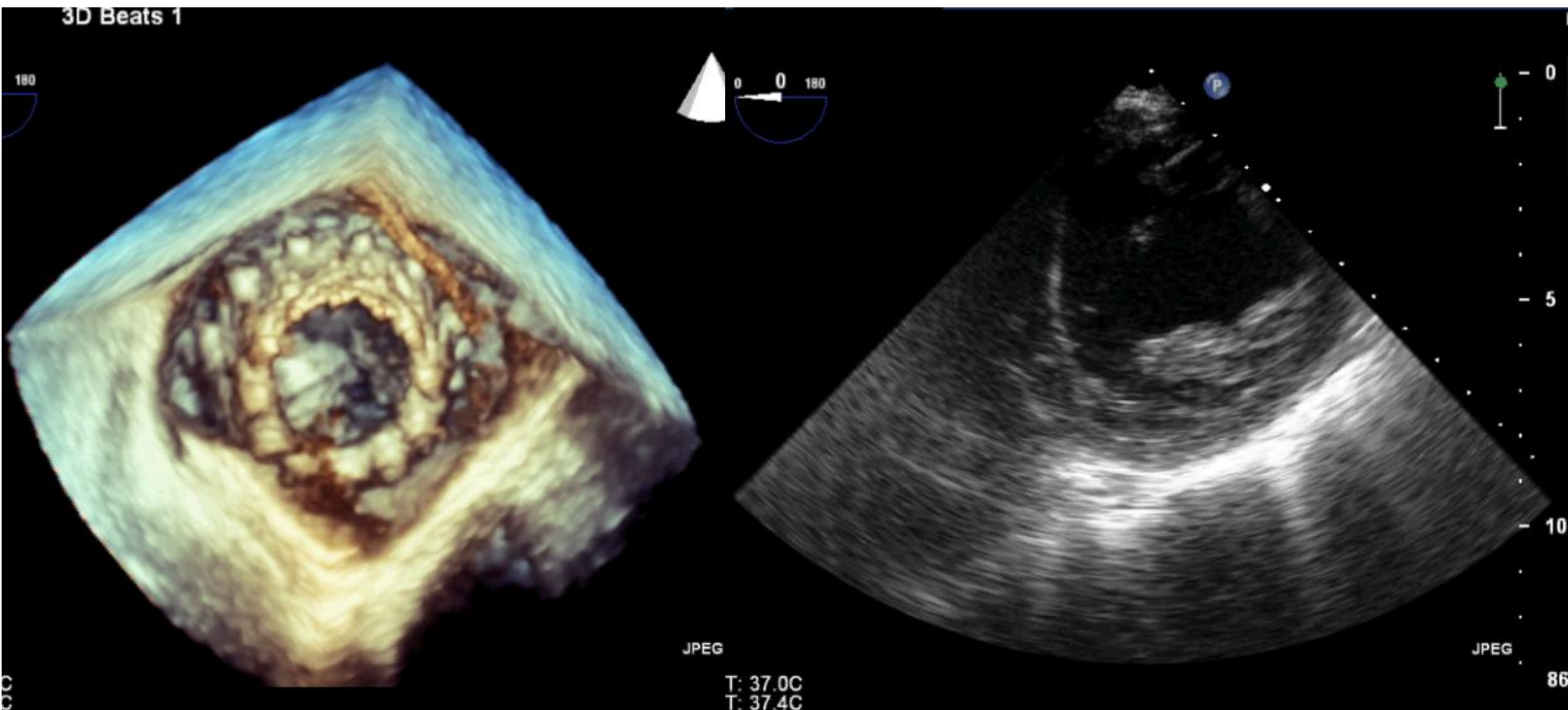


# Valve after deployment



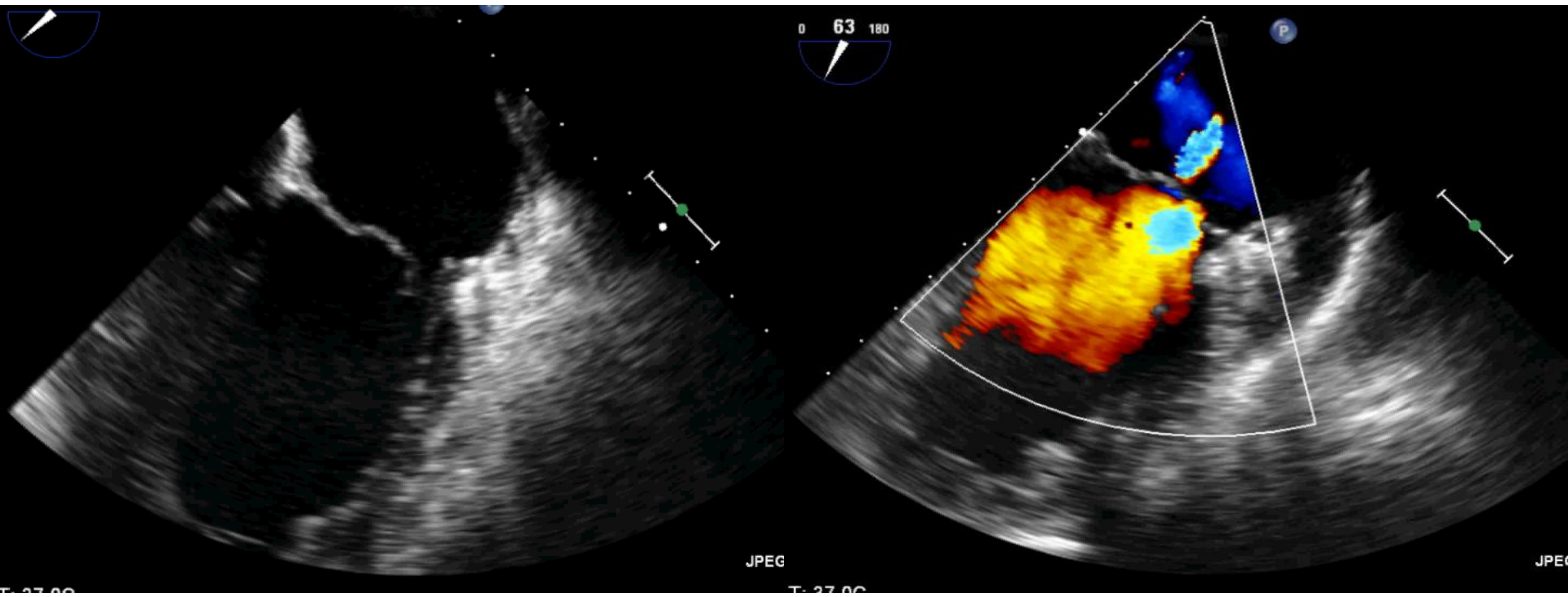
# Echocardiography

## Day 3





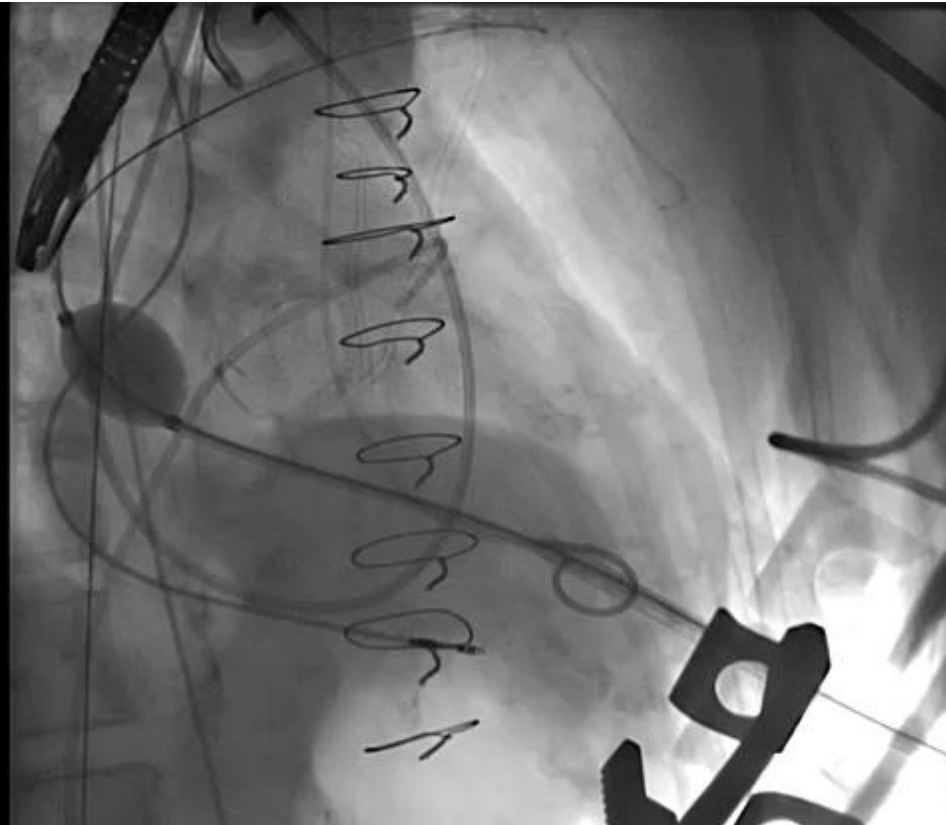
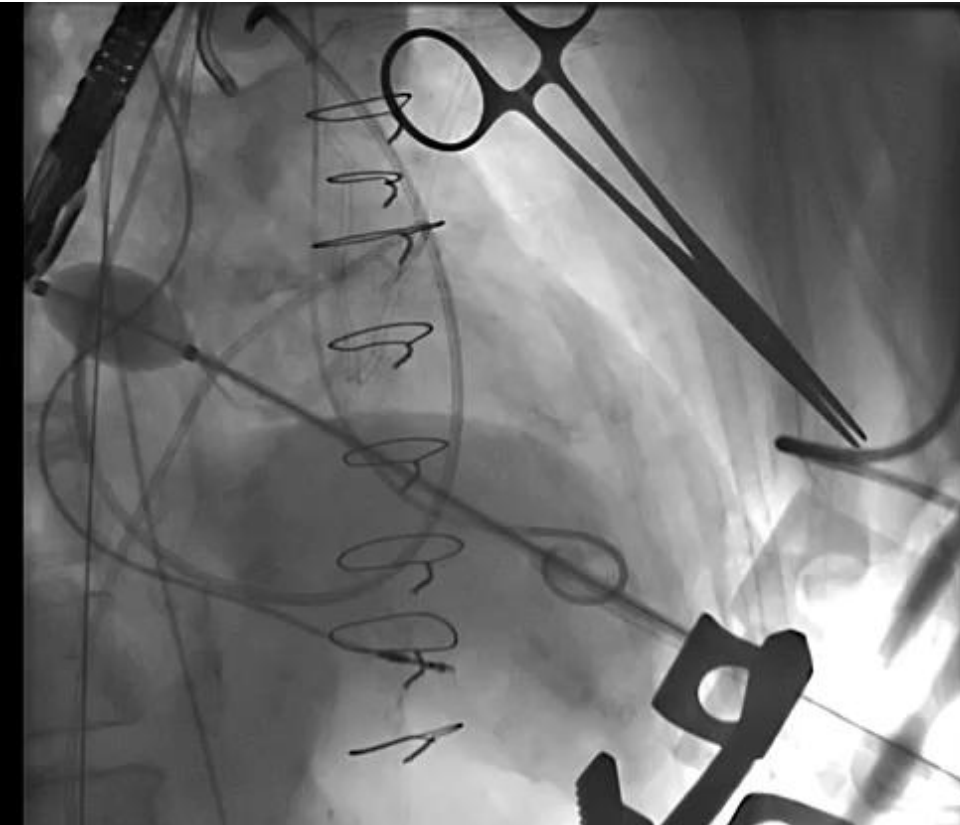
# chordae rupture with prolapse of AML



# Copenhagen manoeuvre

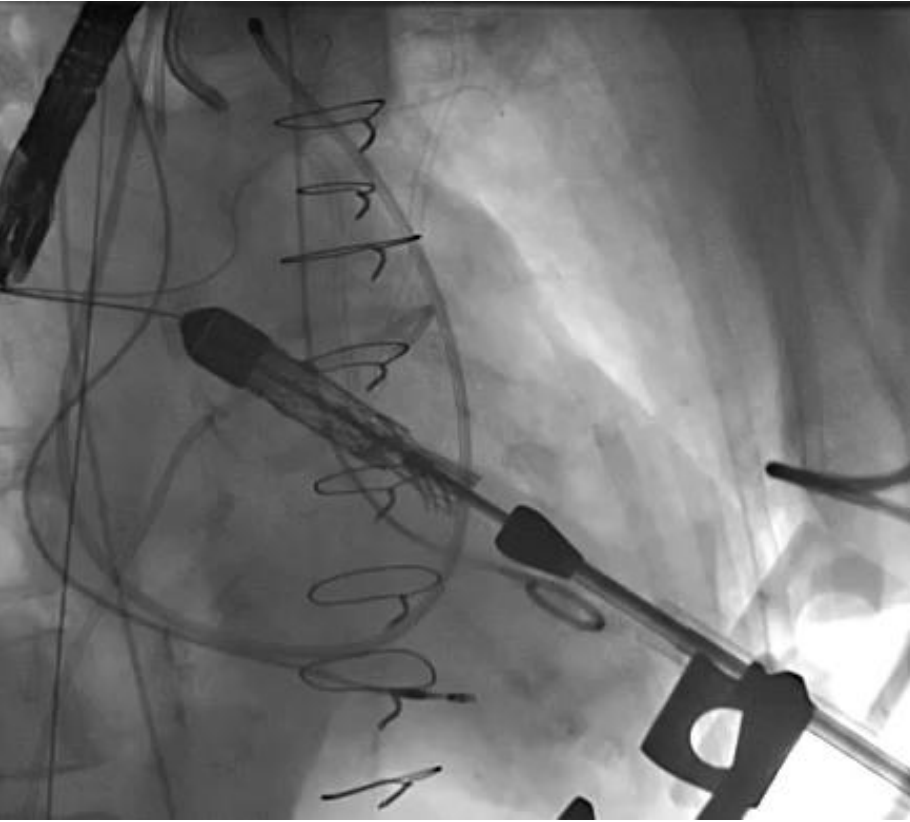
Engaged in mitral apparatus

Free run





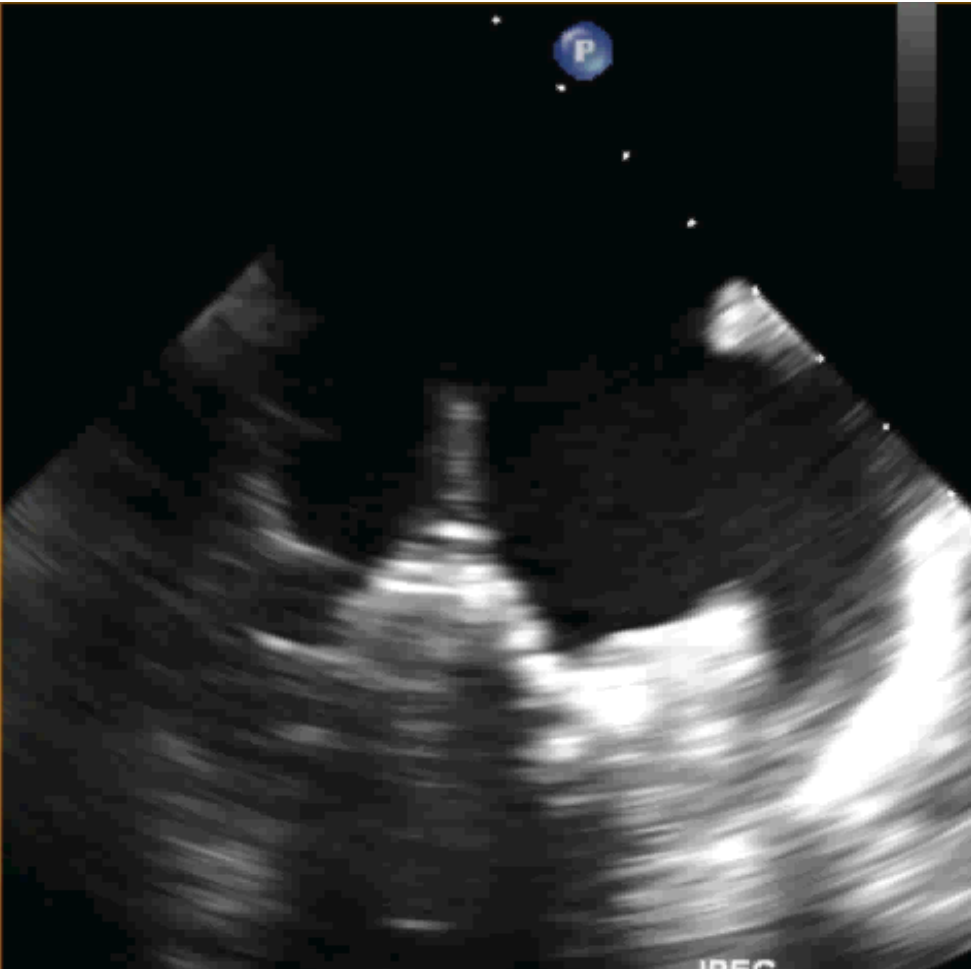
Capsule retrieval



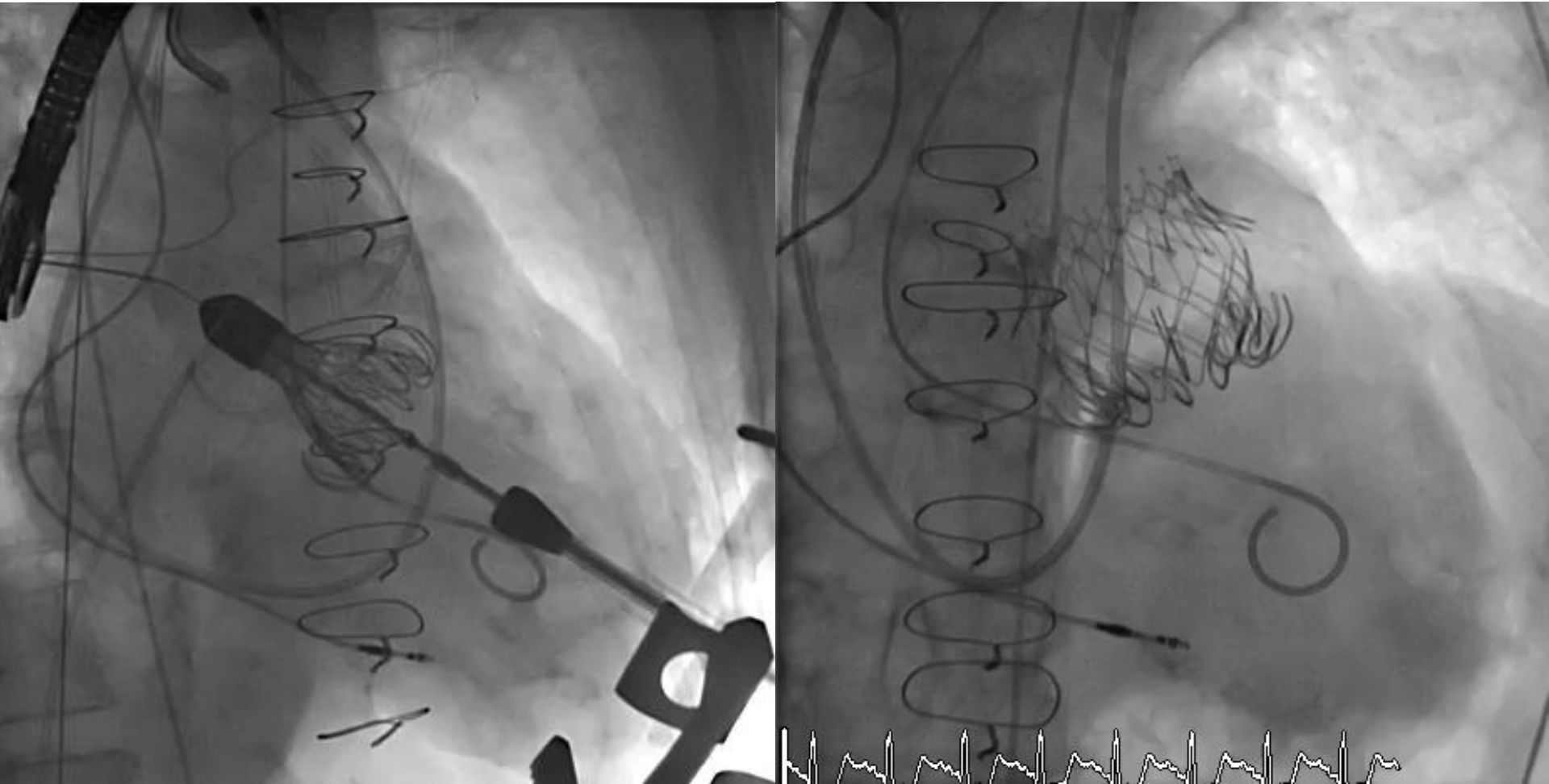
Flipping LV anchors



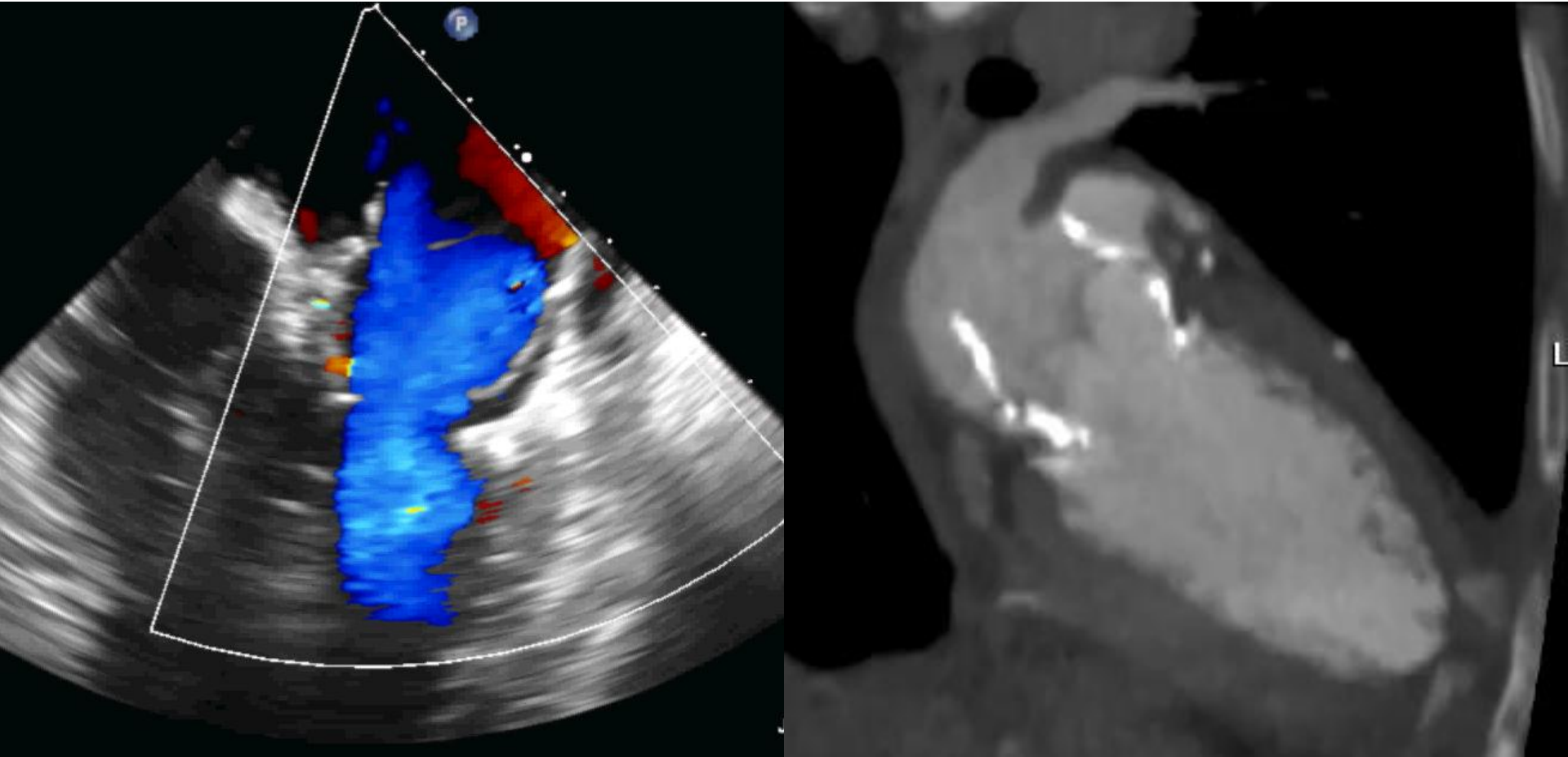
# Secure capture of both leaflets



# Final release

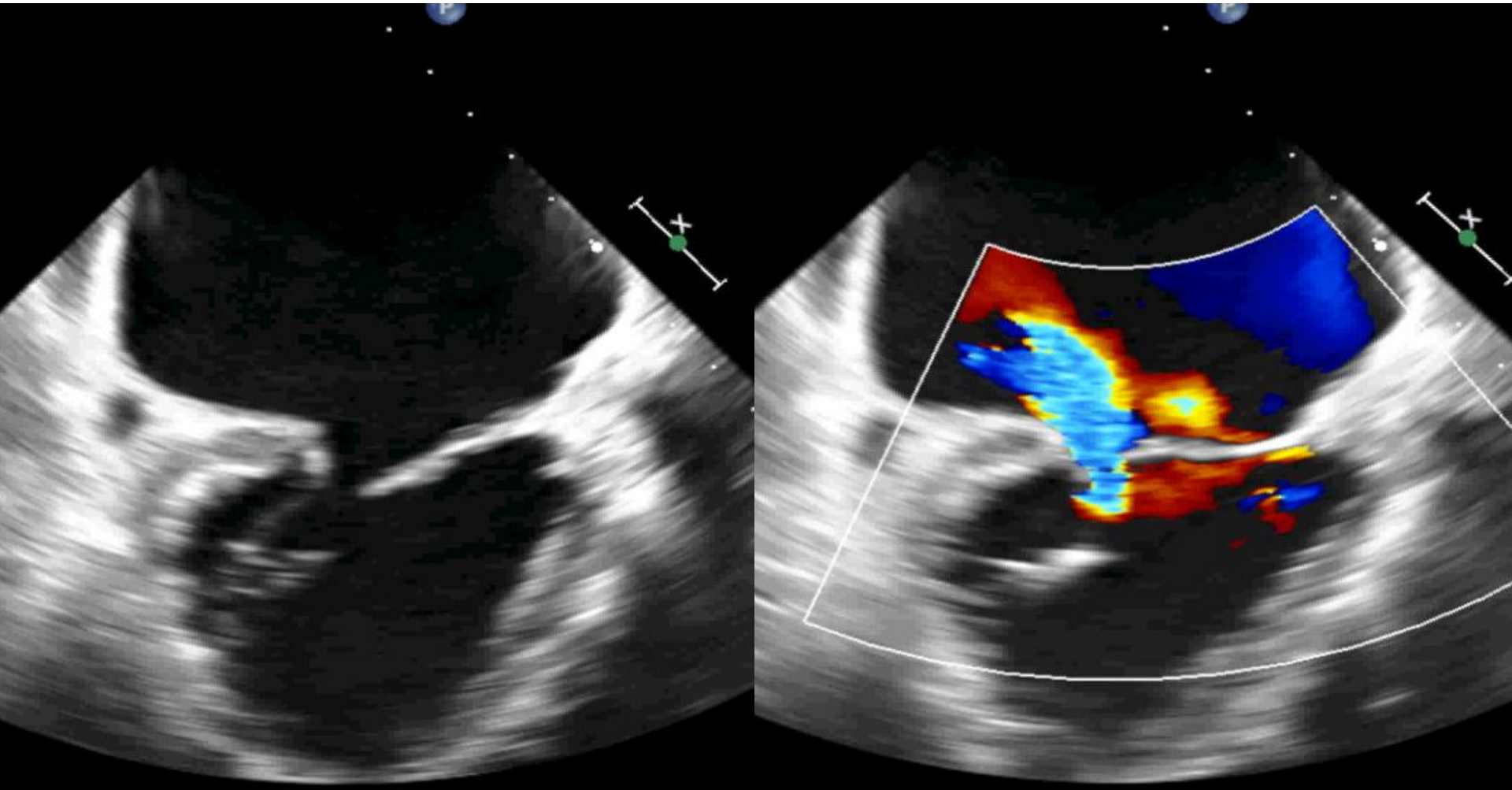


# Post-procedural imaging





# Annular dilatation & restricted PML

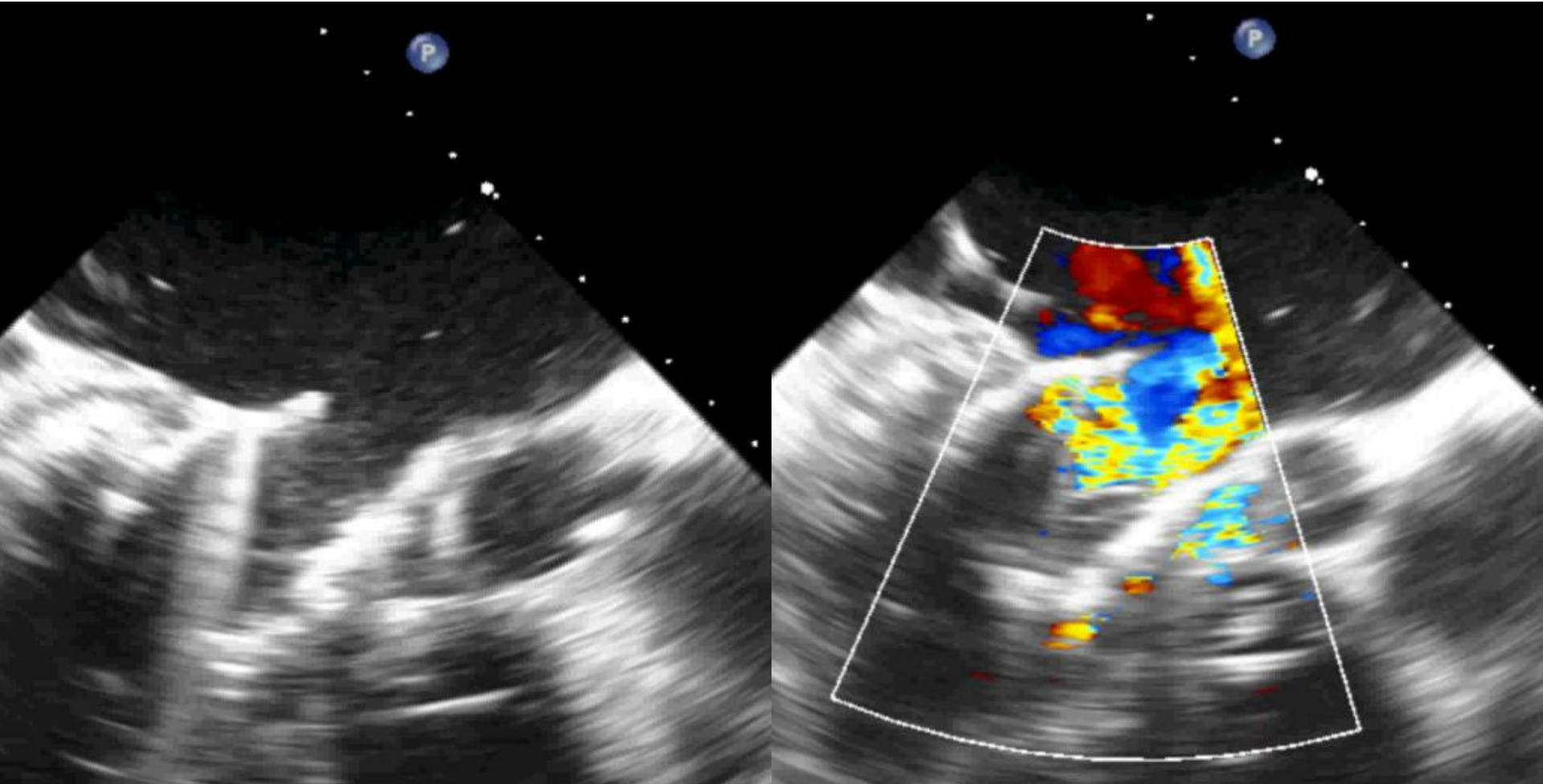


Checking position

Releasing valve

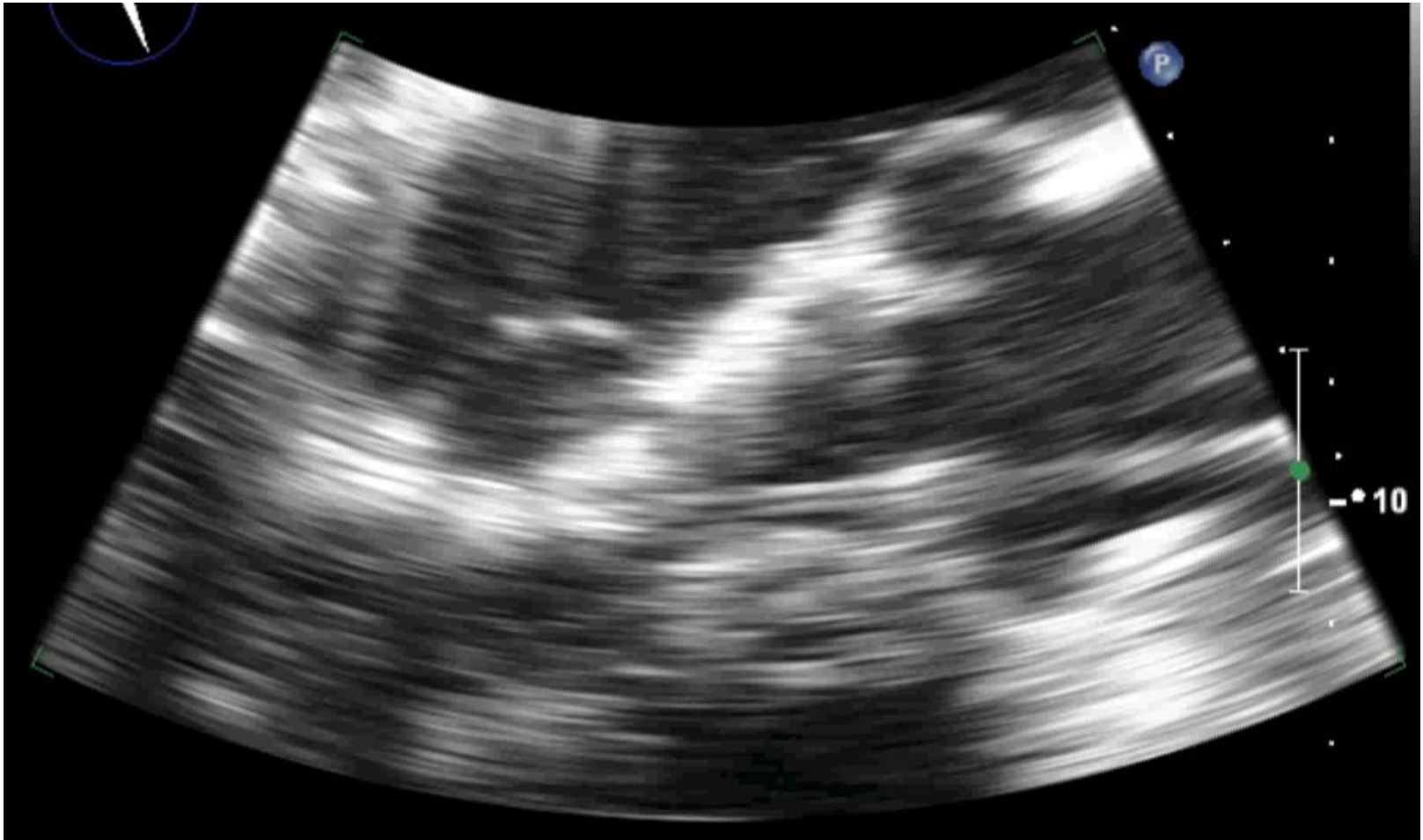


# Low position at aortic side

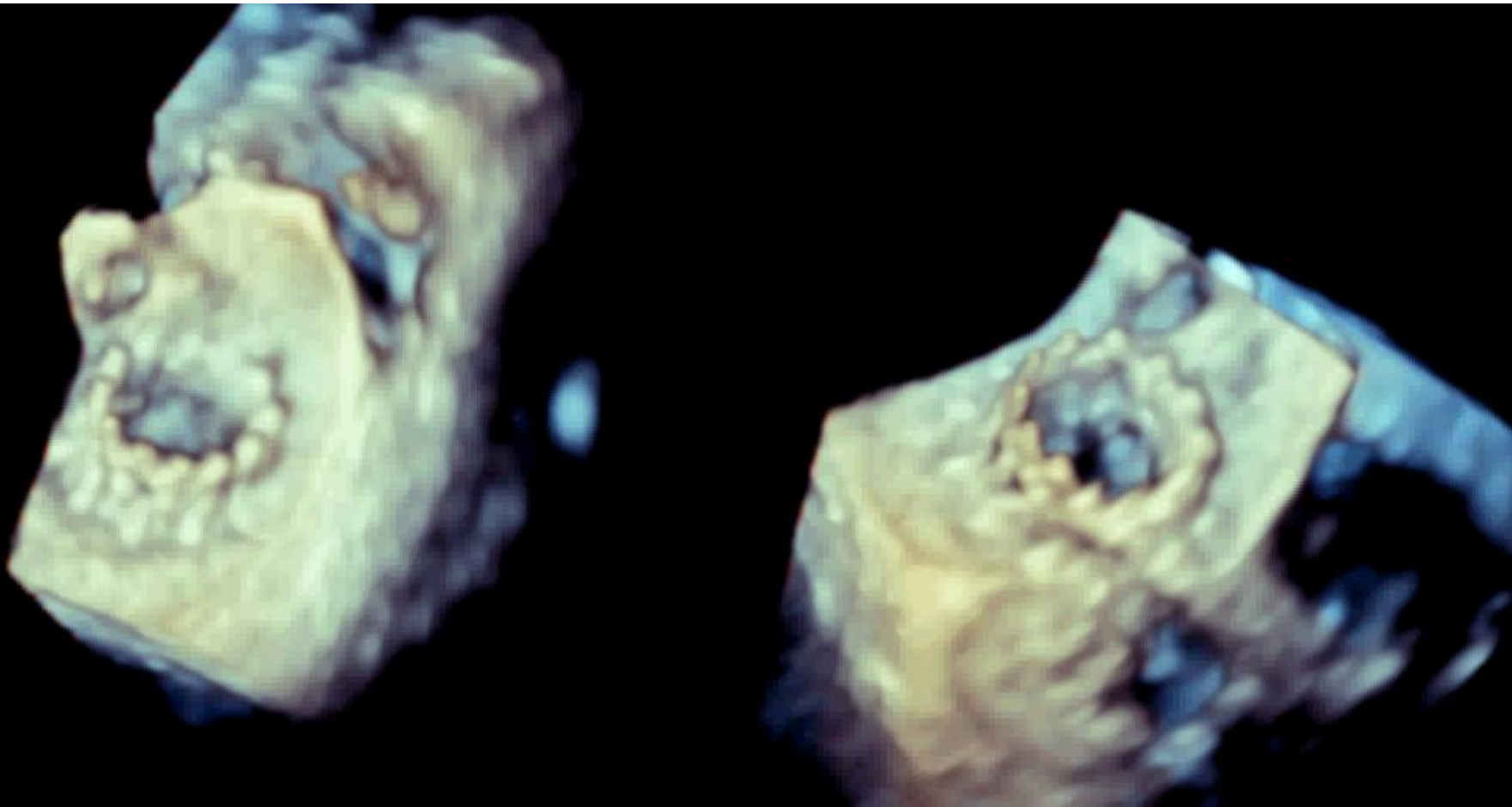




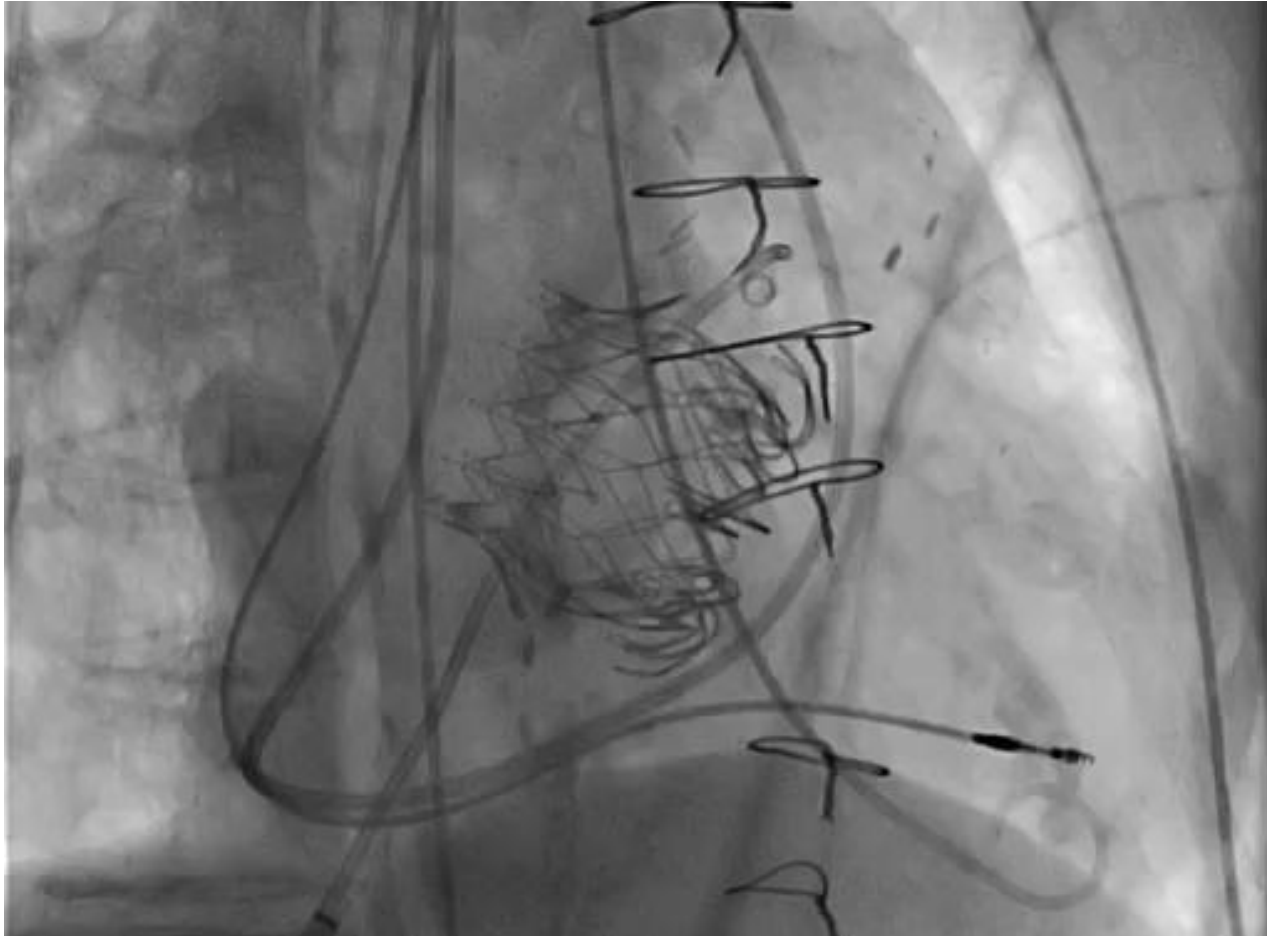
# Snare and pull frame from the aorta



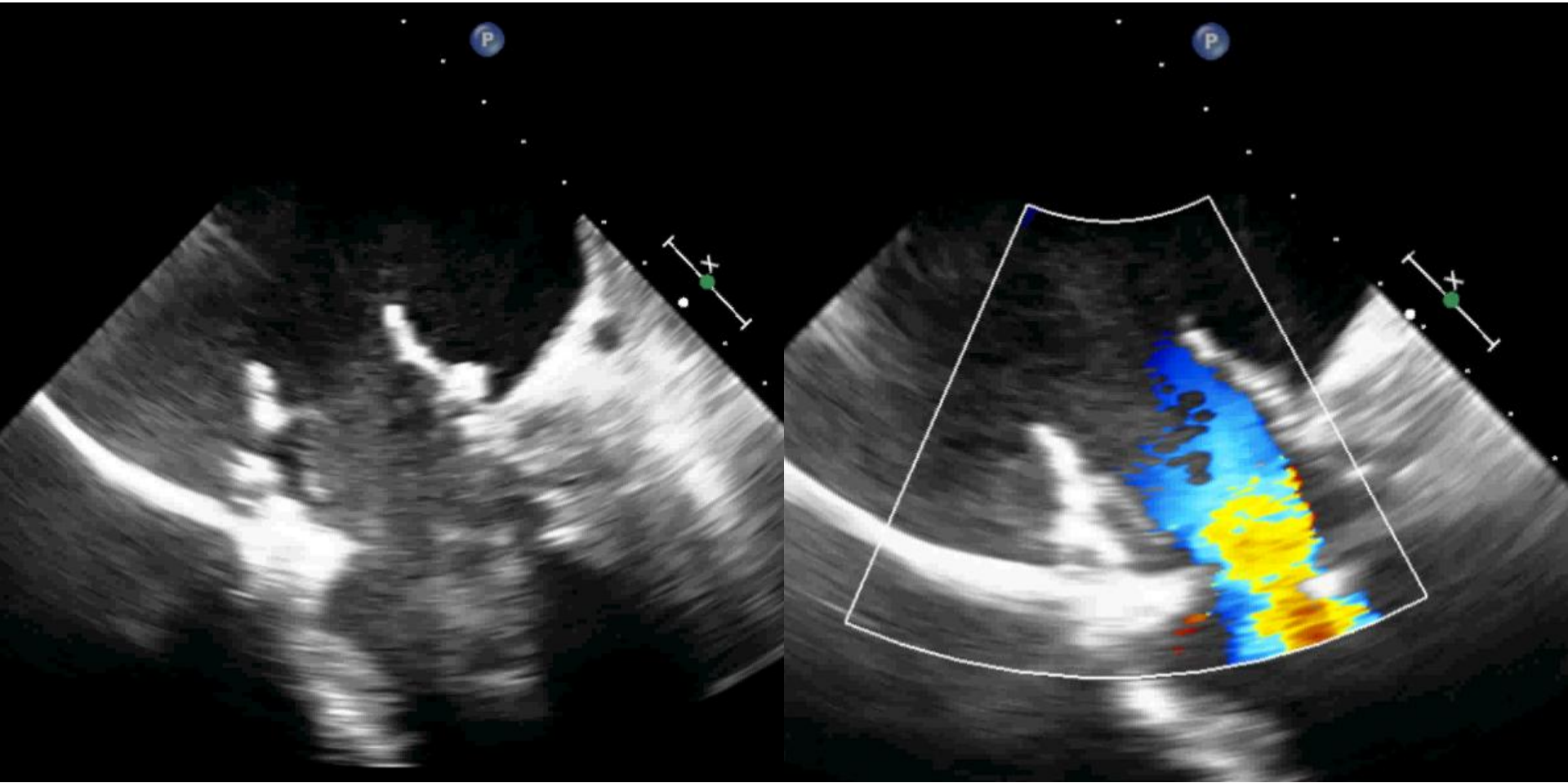
# Corrected position



# Competent valve

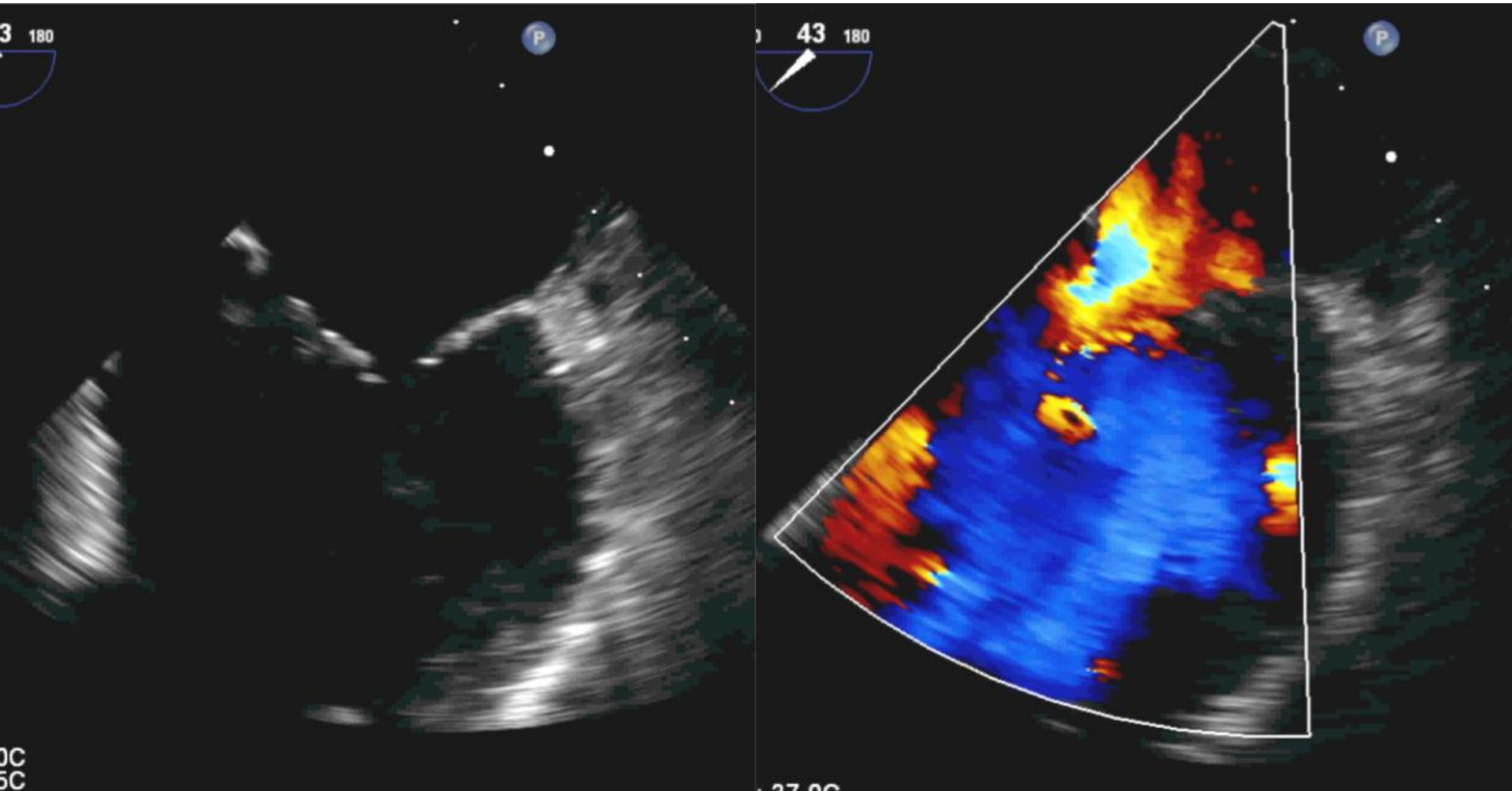


Day 68

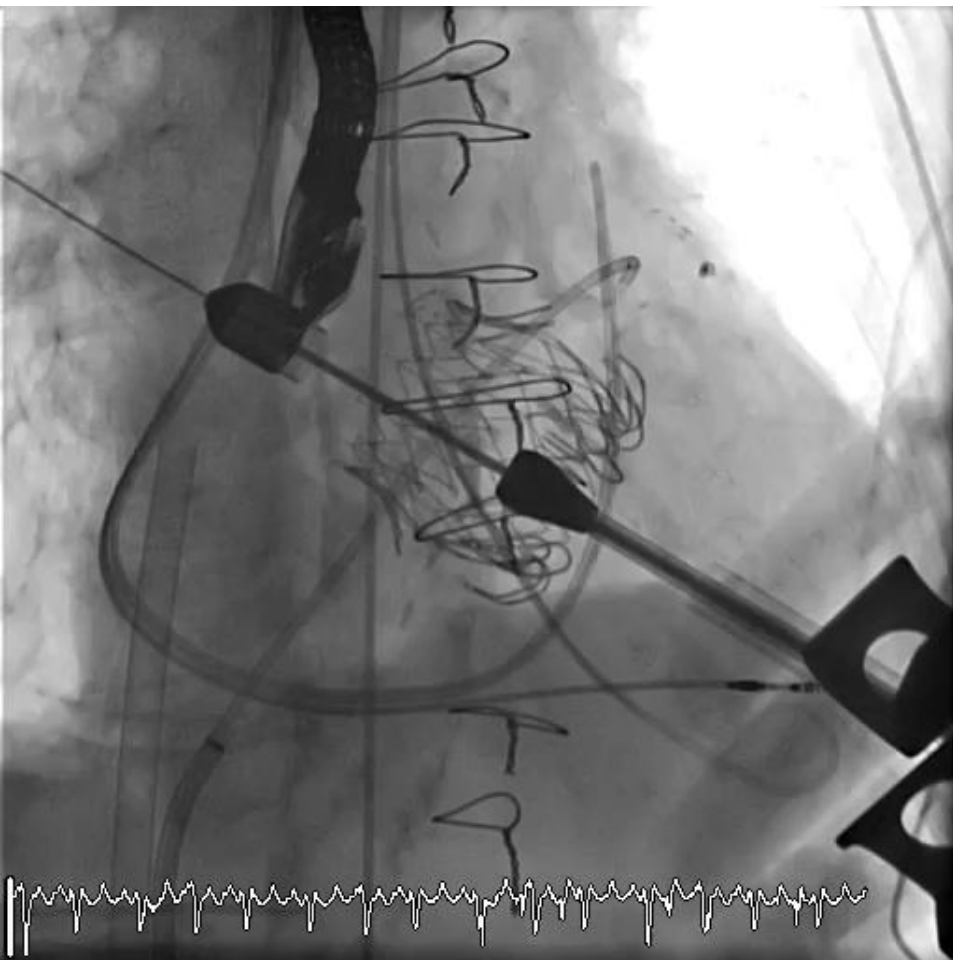




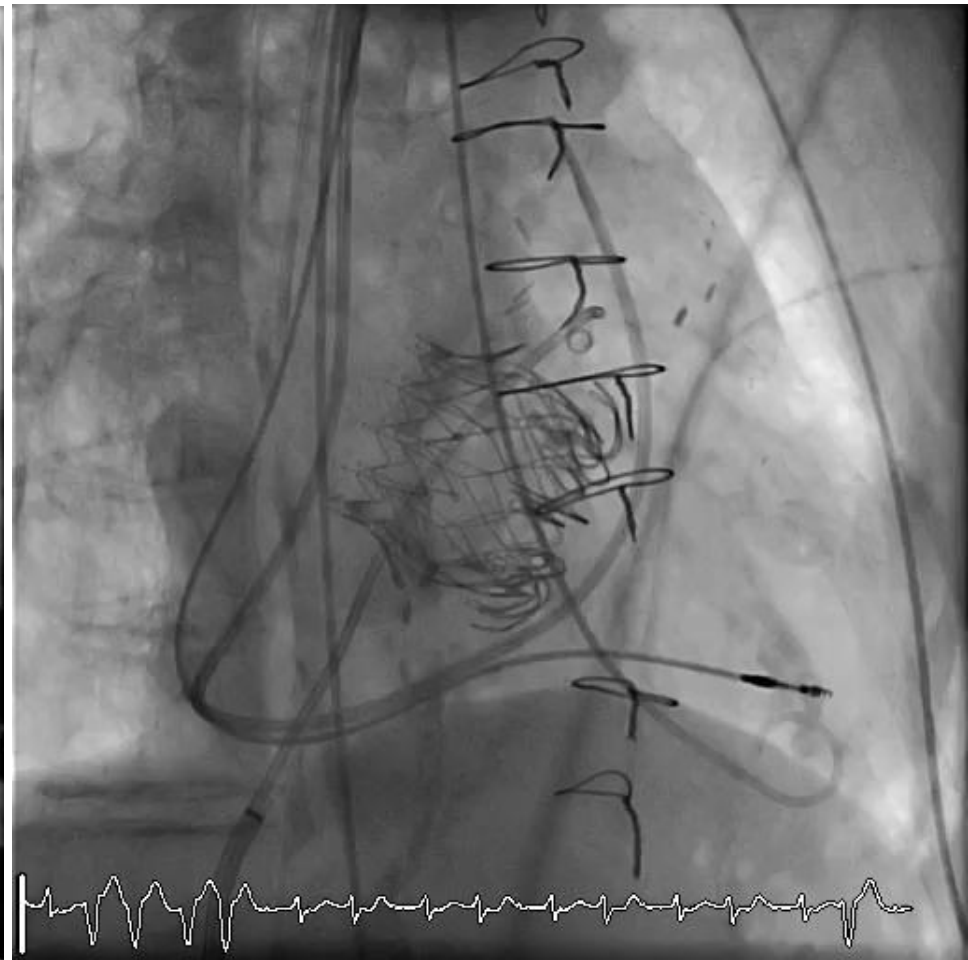
# Annular dilatation



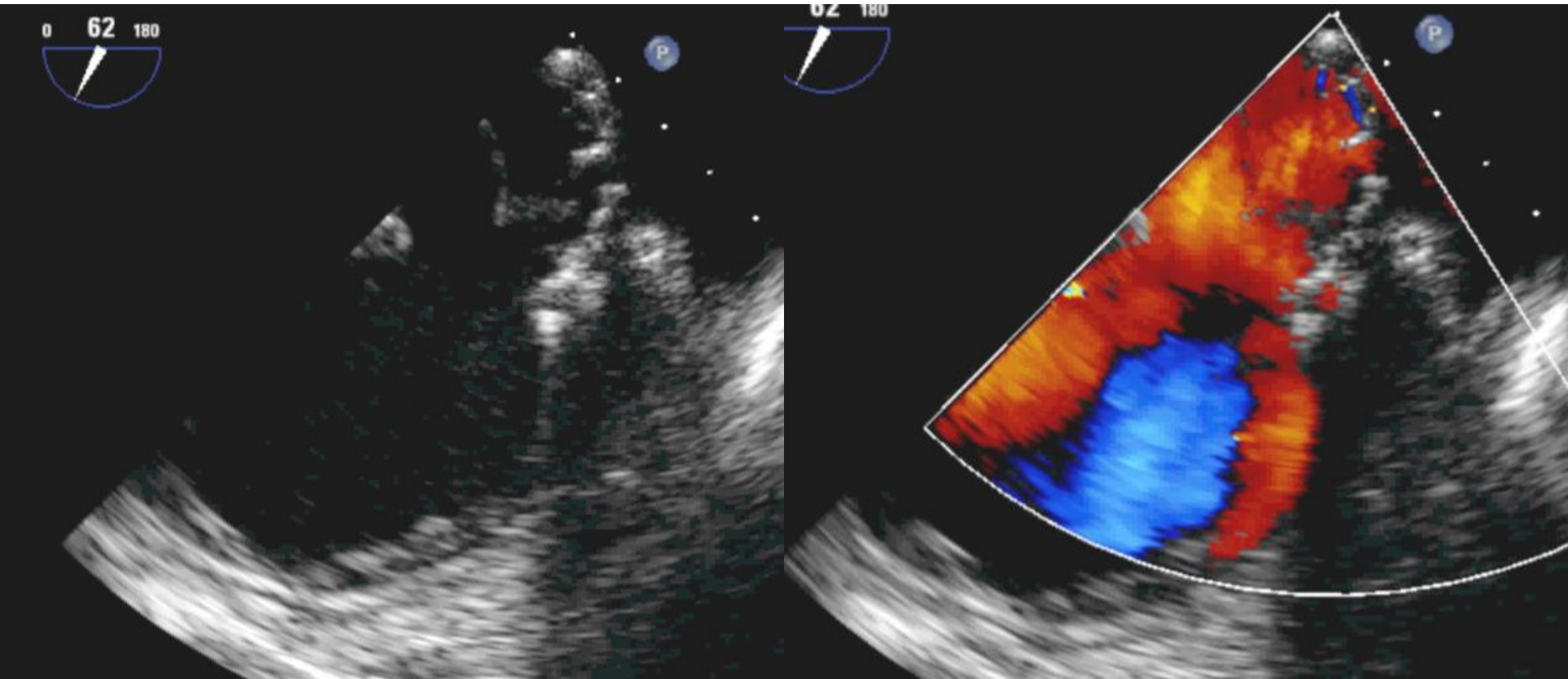
Capsel closure



Ventriculogram



# Post-procedural imaging





# Next steps for CardiAQ

- Gain more experience on both TF and TA TMVR procedure during compassionate cases
- CE mark trial anticipated to start by early 2015
- 100 patients at 10 sites

# Co-workers

## *Cardiologists*

- Nikolaj Ihlemann
- Anders Jönsson
- Olaf Franzen
- Matthew Brooks
- Luigi Biasco
- Ole de Backer

## *Cardiothoracic surgeons*

- Susanne Holme
- Peter Skov Olsen
- Mariann Tang Jensen
- Kim Terp

## *Anaesthesiologists*

- Peter Bo Hansen
- Peter Hasse Møller
- Annette Ulrich

## *Nurses*

- Birgit Lauridsen
- Pia Mejding
- Barbara Wulff

## *CardiAQ*

- Arshad Quadri
- Brent Ratz

# Copenhagen FIH Team - 2012



# Issues for TMVI

- Access route
- Size of delivery system
- Steerability
- Anchoring
- Re-capture
- Anti-coagulation/platelet therapy
- Patient selection
- Role in spectrum of repair/replacement techniques