Initial Experience with Transcatheter Mitral Valve Replacement - The Tendyne System

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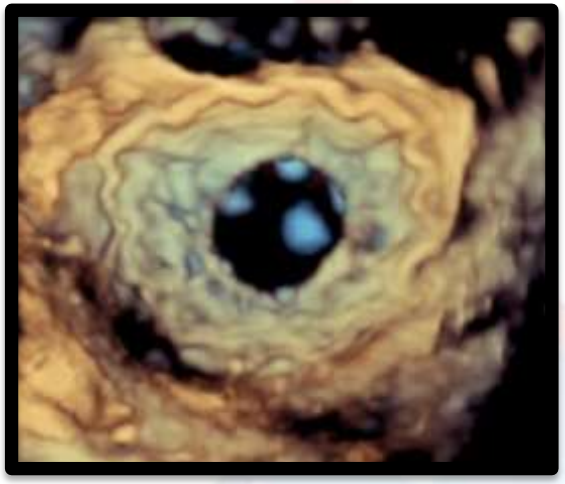
The Prince Charles Hospital

Tendyne Transcatheter Mitral Valve

Tendyne Device

- D-Shaped Self-Expanding Nitinol Outer Frame
  - Designed to conform with native MV anatomy
- Symmetrical Porcine Pericardial Tri-Leaflet Valve
- Large Valve Size Matrix
  - Single inner valve size
  - Multiple outer frame sizes 30-43mm A34-50mm CC
- Large Effective Orifice Area (>3.0cm^2)
  - Larger EOA than any surgical valve
- Valve Tether to Apex
  - Provides valve stability, designed to reduce PVL
- Apical Pad assists in Access Closure
- Rigorous pre-clinical durability and biocompatibility studies



Global Feasibility Study of the Tendyne Mitral Valve System

- St Vincent's Hospital, Sydney, Australia
  - David Muller, Paul Jansz, Marty Shaw
- Minneapolis Heart Institute at Abbott Northwestern Hospital, Minneapolis, Minnesota
  - Wesley Pedersen, Paul Sorajja, R. Saeid Farivar, Benjamin Sun, Richard Bae
- Prince Charles Hospital, Brisbane, Australia
  - Darren Walters, Andrew Clarke, Gregory Scalia
- Baylor Heart and Vascular Institute, Dallas, Texas
  - Paul Grayburn, Robert Stoler, R. Hebeler
- Oslo University Hospital, Oslo, Norway
  - Gry Dahle, Kiell Arne Rein

Global Feasibility Study of the Tendyne Mitral Valve System

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The Tendyne Early Feasibility Trial of Transcatheter Mitral Valve Replacement for Severe Mitral Regurgitation

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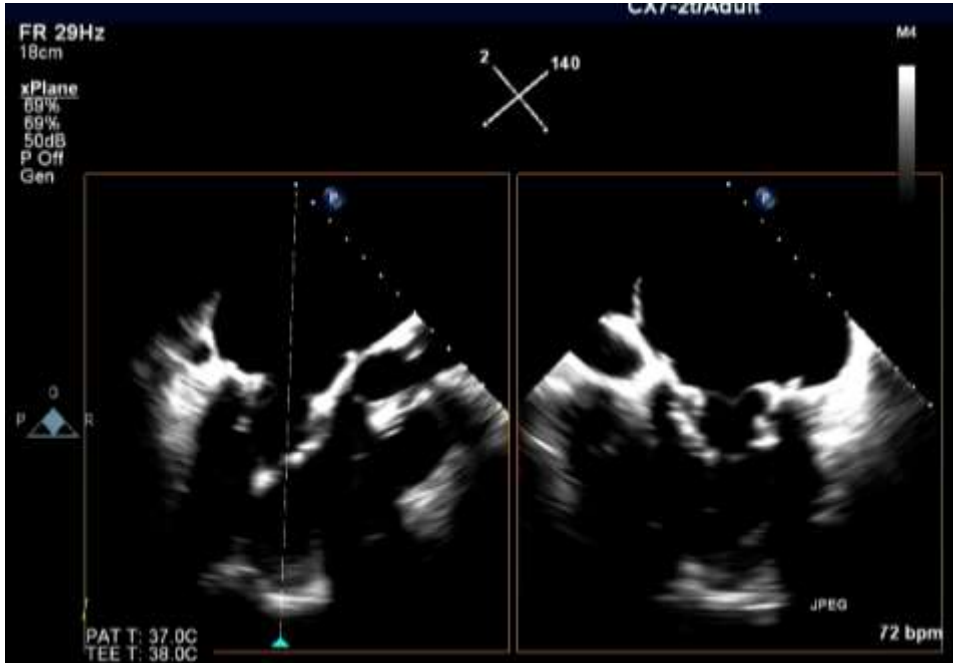
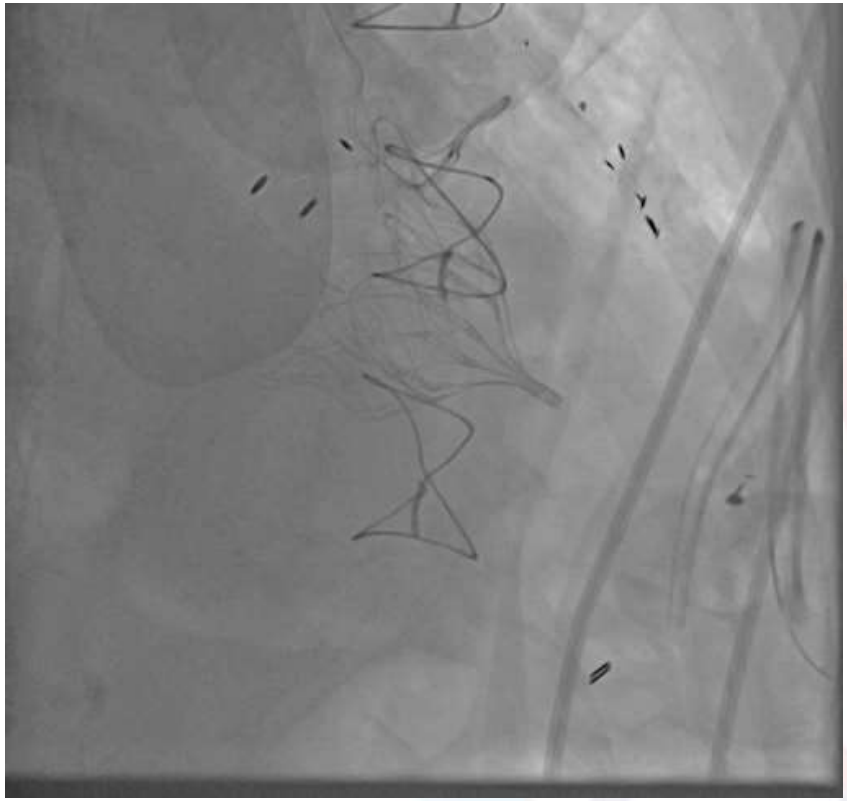
Abstract:
Background. Severe mitral regurgitation (MR) is associated with a high morbidity and mortality. Therapeutic options for high surgical risk patients are limited. This study evaluated transcatheter mitral valve replacement (TMVR) in patients with severe MR at high risk for surgery.
Methods. The Tendyne Early Feasibility study is a prospective, non-randomized trial evaluating a novel mitral valve prosthesis. The device consists of a D-shaped outer frame, a circular inner frame, and a porcine pericardial trileaflet valve. It is deployed from a trans-apical approach within the mitral annulus and is secured using a tether affixed to the apex of the left ventricle (LV). The valve is recapturable, repositionable, and fully retrievable. Eligibility criteria for the study included symptomatic grade 3 or 4 MR, LV ejection fraction (LVEF) $\geq$30%, LV end-diastolic dimension <7.0cm, and high or prohibitive surgical risk. Exclusions included prior mitral or aortic valve surgery, severe coronary disease, heart failure requiring inotropic support, and severe tricuspid regurgitation or right ventricular dysfunction.
Results. To date, 21 patients (20 male; age 77.1yrs (range 55.1-91.4)) have been treated at 5 study sites. All had symptomatic grade 3 or 4 MR that was secondary (n=18), primary (n=1), or of mixed pathology (n=2). The LVEF was 43.2$\pm$12.4% and the STS score was 10.0$\pm$13.4%. In 19 patients (90.5%), the device was deployed with no residual MR. Device deployment was not stable in one patient, and resulted in LV outflow obstruction in another. In both cases, the device was removed without adverse sequelae. Three patients (14.3%) required peri-procedural transfusion. There was one death at post-operative day 13 due to sepsis. The other 20 patients were discharged after a length of stay between 5 and 12 days. At 30 days, there were no further deaths, no strokes, no paravalvular leak or haemolysis, and no need for MV surgery.
Conclusions. These early results from the Feasibility Trial suggest that the Tendyne TMVR system can be used to safely and effectively treat symptomatic MR in a high-risk population.

Global Feasibility Study of the Tendyne Mitral Valve System

Tendyne Transcatheter Mitral Valve





Global Feasibility Trial Organisation

DSMB/CEC:

John Carroll (Chair), Isaac George, Emil Missov

Echo Core Lab:

Beth Israel Deaconess MC, Boston (Jeff Popma)

CT Core Lab:

St Paul's Hospital, Vancouver (Jonathon Leipsic, Philippe Blanke)

Tendyne Global Feasibility Trial

Inclusion criteria:

1. Severe mitral valve regurgitation of primary or secondary etiology
2. NYHA functional class II, III or ambulatory IV
3. Age ≥18yrs, able to provide informed consent
4. High risk for cardiac surgery as determined by the Heart team (including Cardiologist and Cardiac Surgeon)
5. Not ideal candidate for MitraClip

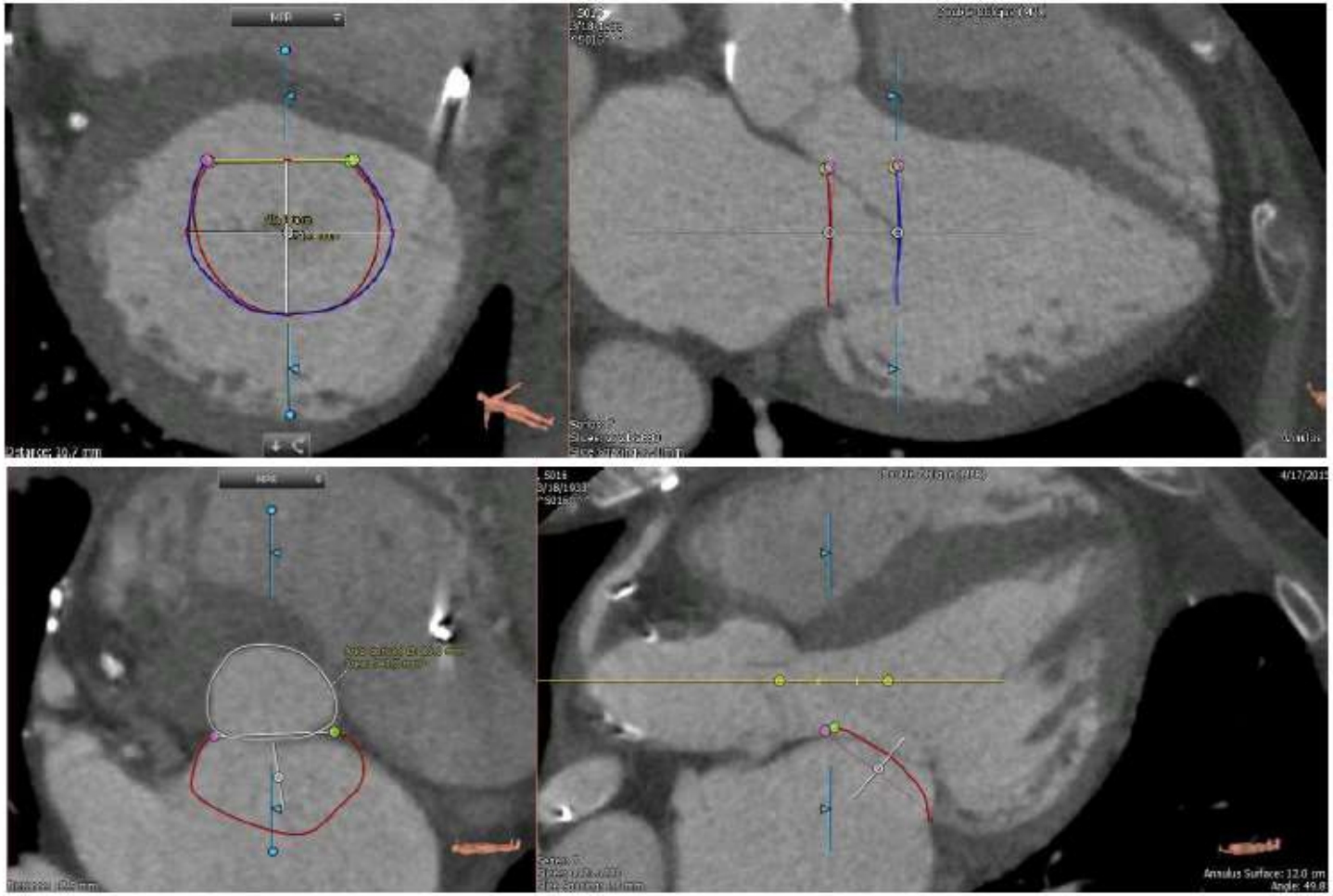
Exclusion criteria:

1. Severe mitral annular or valvular calcification/stenosis, vegetation or mass
2. Largest annular dimension >45mm, LVEDD <45mm or >70mm
3. LVEF<25%, severe TR/RV dysfunction/pulmonary HT
4. Prior aortic or mitral valve surgery
5. Small neo-LVOT (echo, CT, 3D modeling)

Transthoracic and TOE echo

Preprocedural CT

Tendyne TMVI: Baseline CT



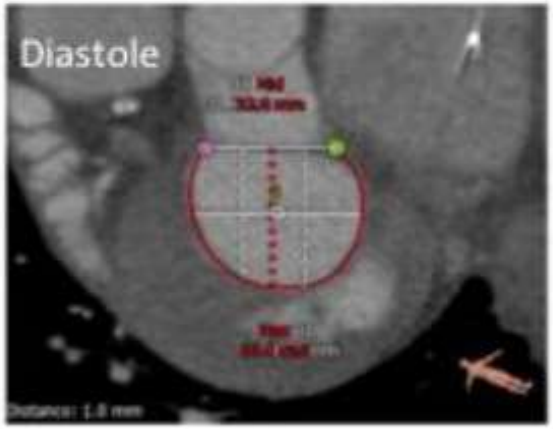
CC: 45.4mm
AP: 34.1mm

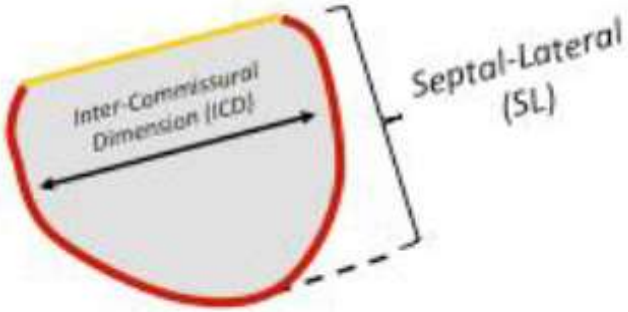
Neo LVOT: 544mm^2

Courtesy P. Blanke, Vancouver

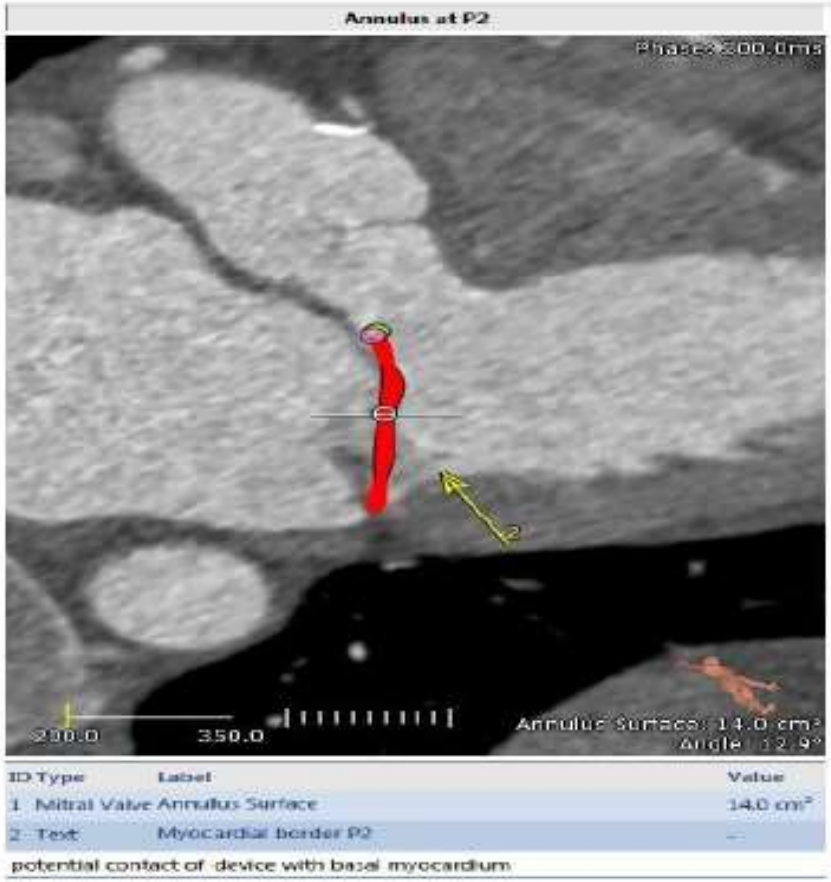
Mitral Orifice Dimensions at Diastole

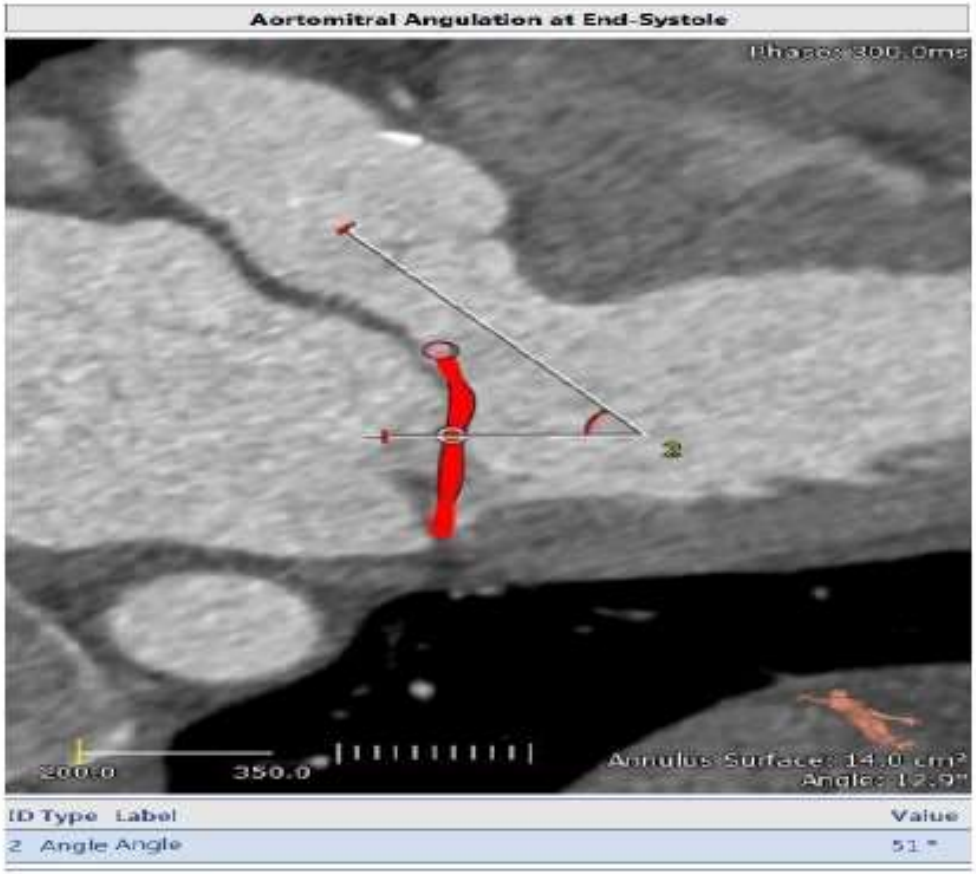
Item	SL (mm)	SL Oversize	ICD (mm)	ICD Oversize	Perimeter (mm)	Perimeter Oversize
Mitral Dimensions (CT Imaging)	33.4	-	40.4	-	125	-
Valve 04	32.5	-3%	43.5	8%	130	4%
Valve 09	34.5	3%	45.5	13%	138	10%
Valve 10	34.5	3%	48.5	20%	144	15%
Valve 15	36.5	9%	49.5	23%	150	20%



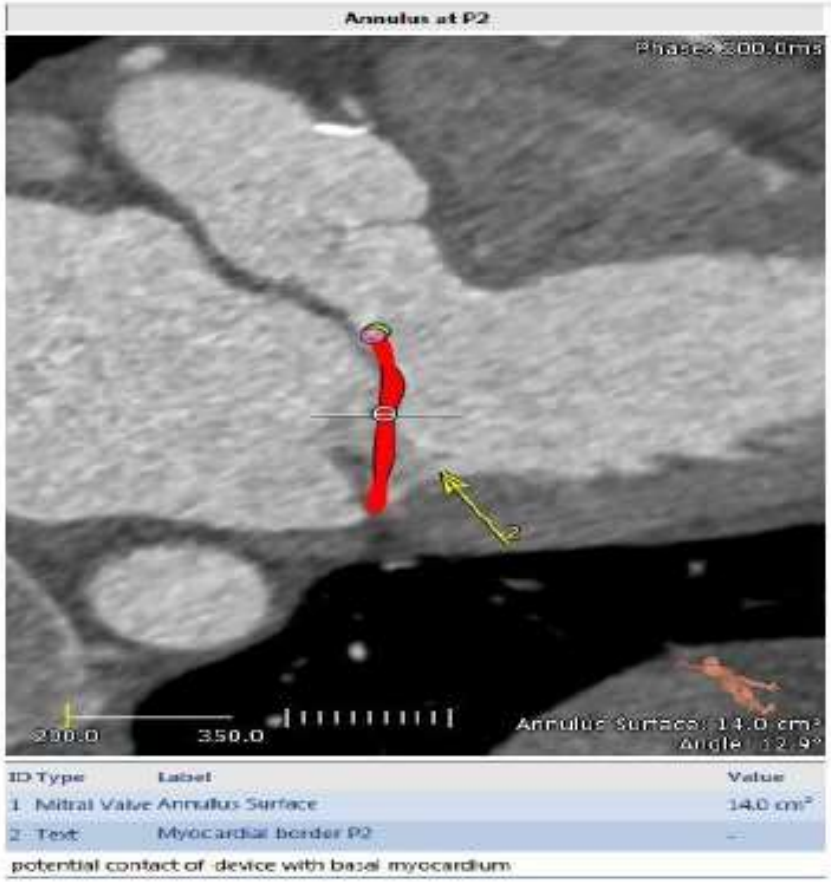


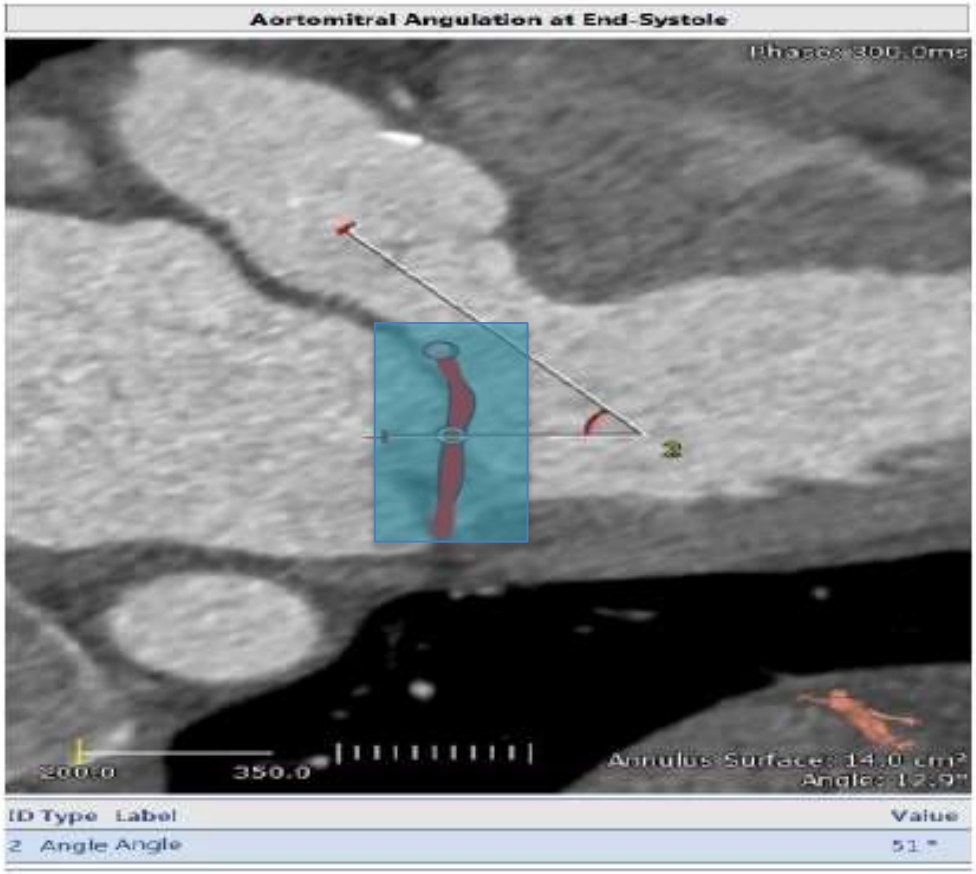
Aortomitral Angulation



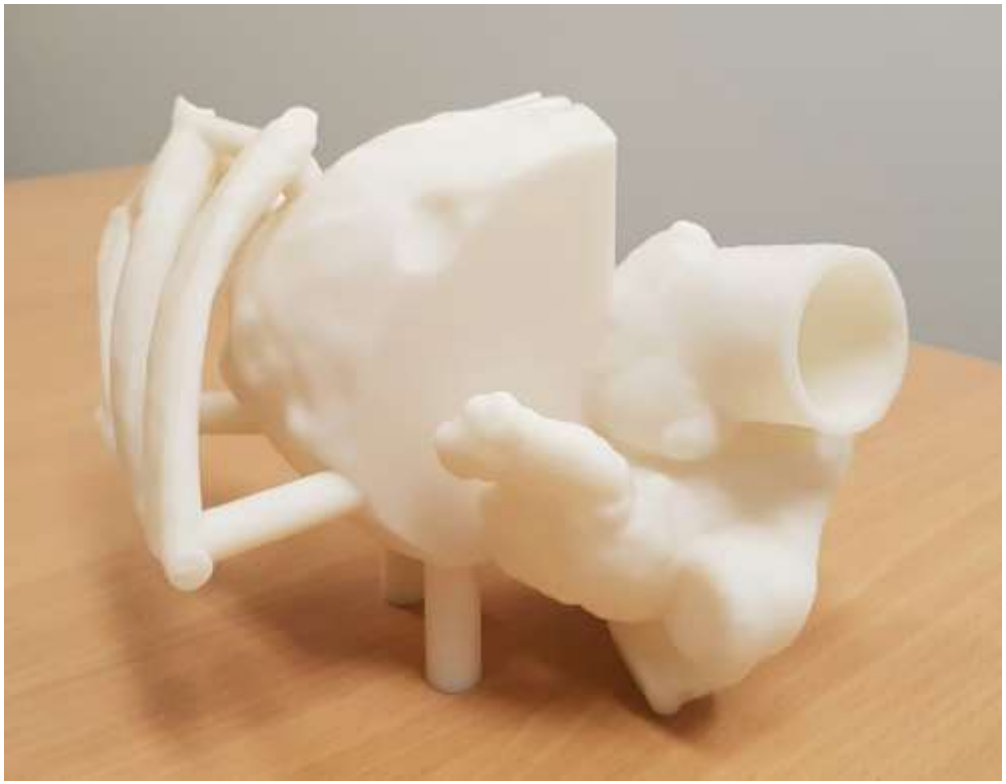


Aortomitral Angulation

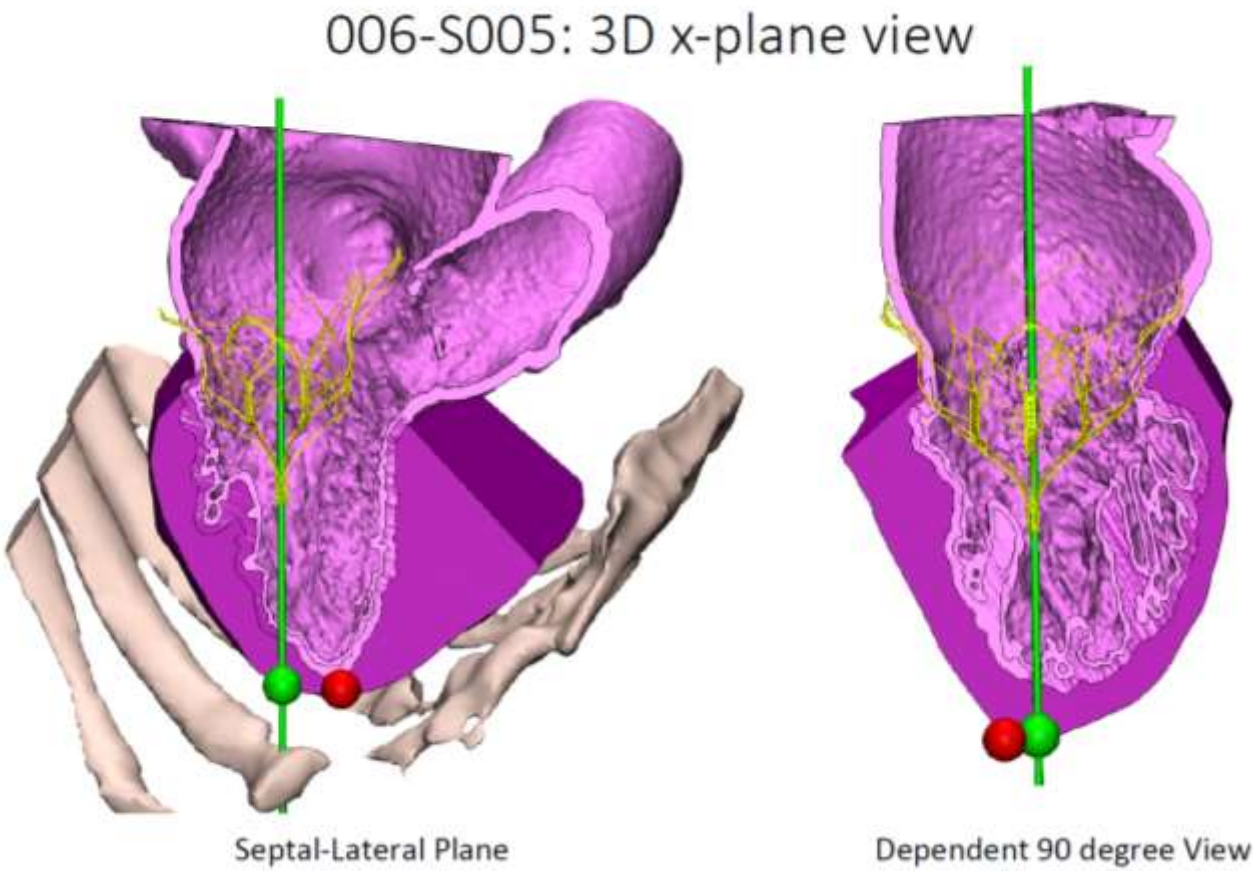




Pre – Procedure Planning

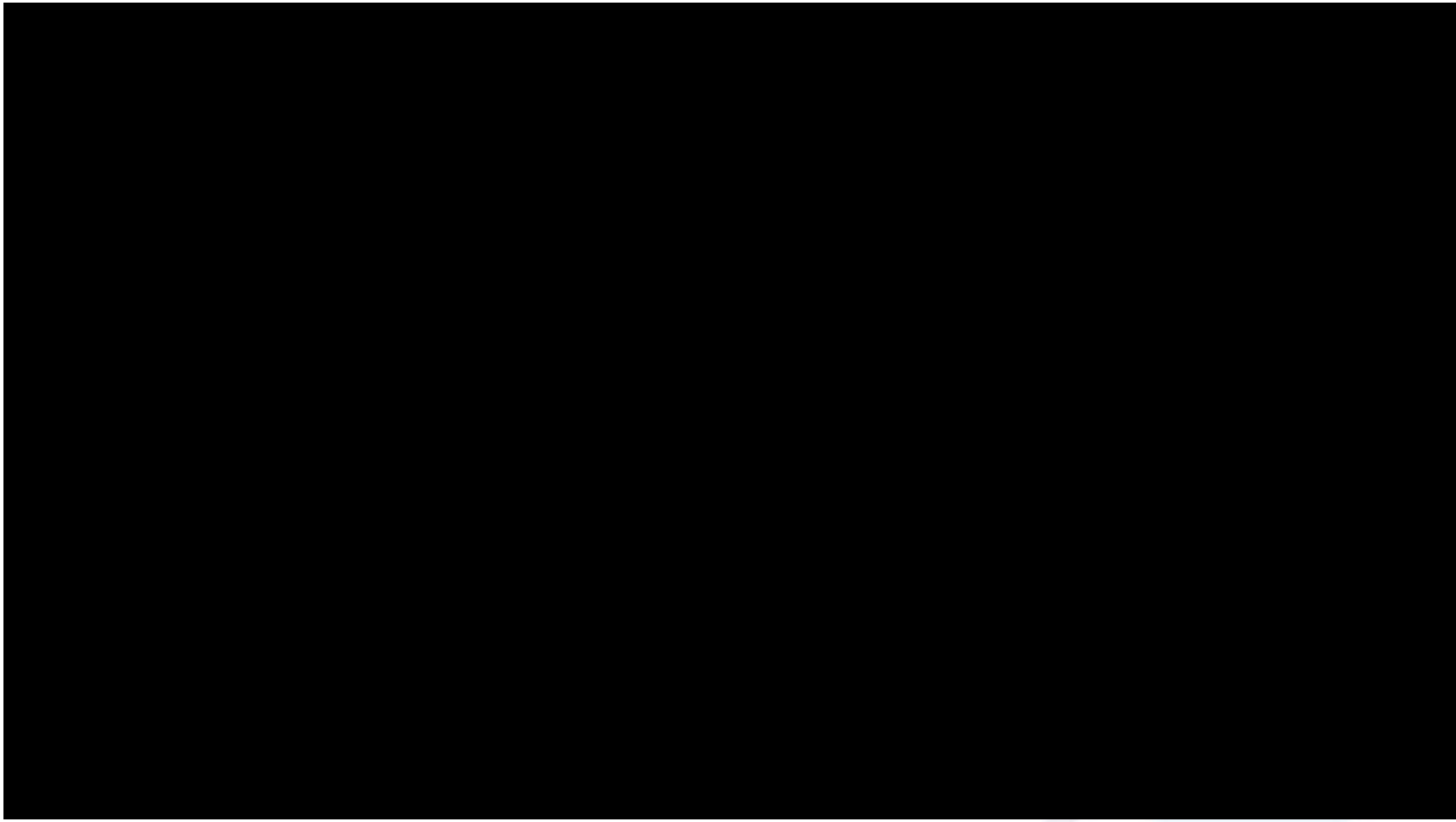


Pre – Procedure Planning

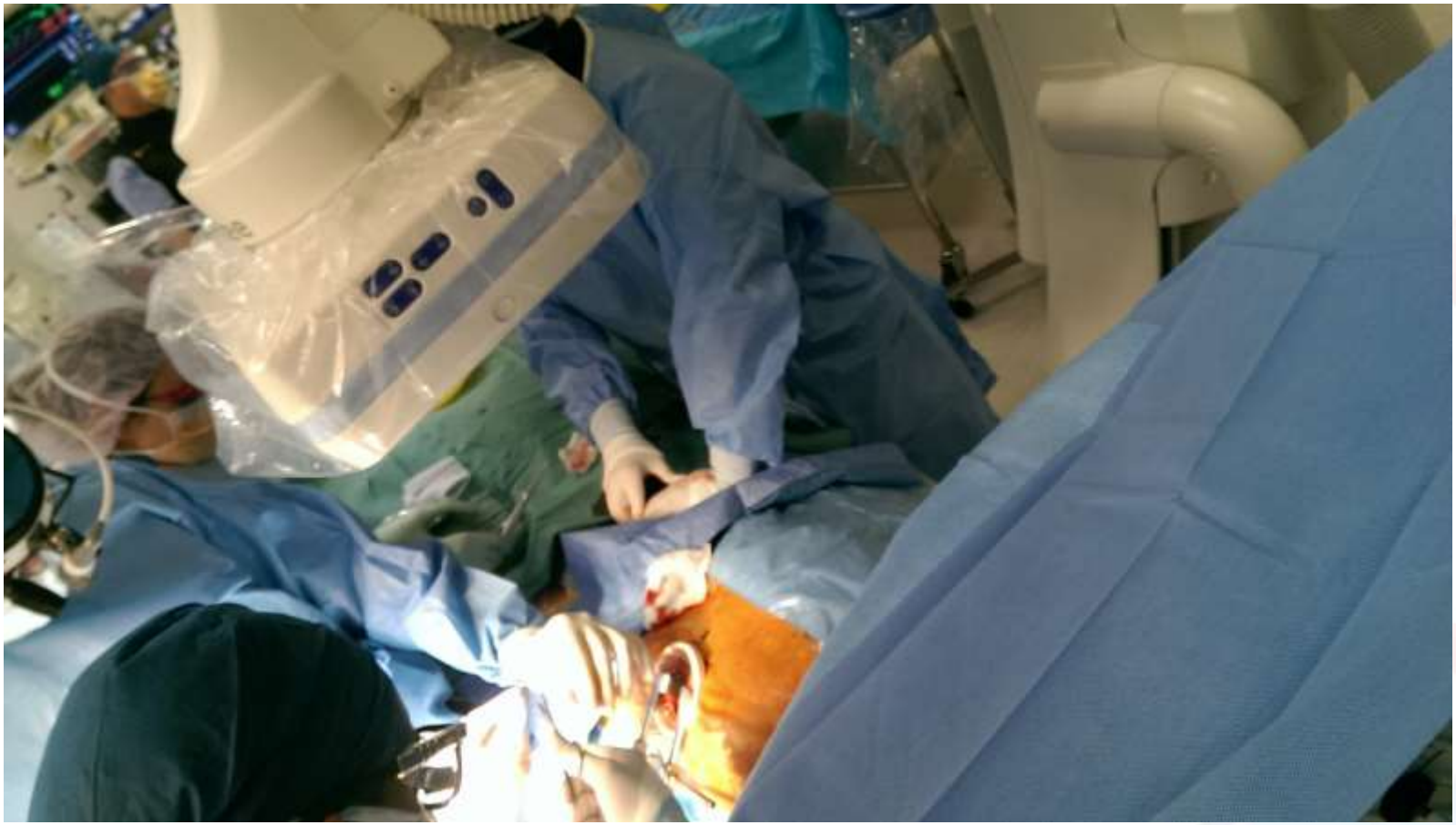


Procedure

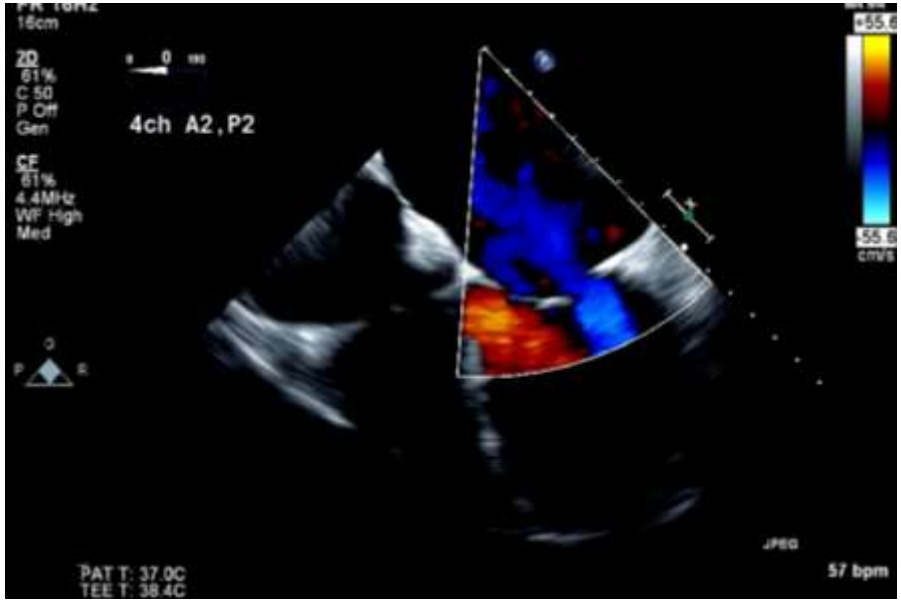
Step by step animation

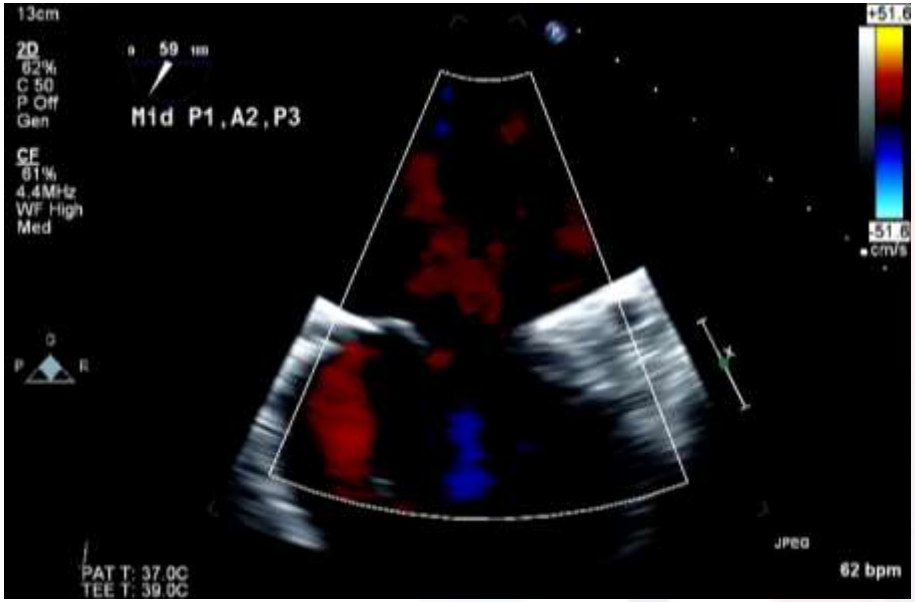


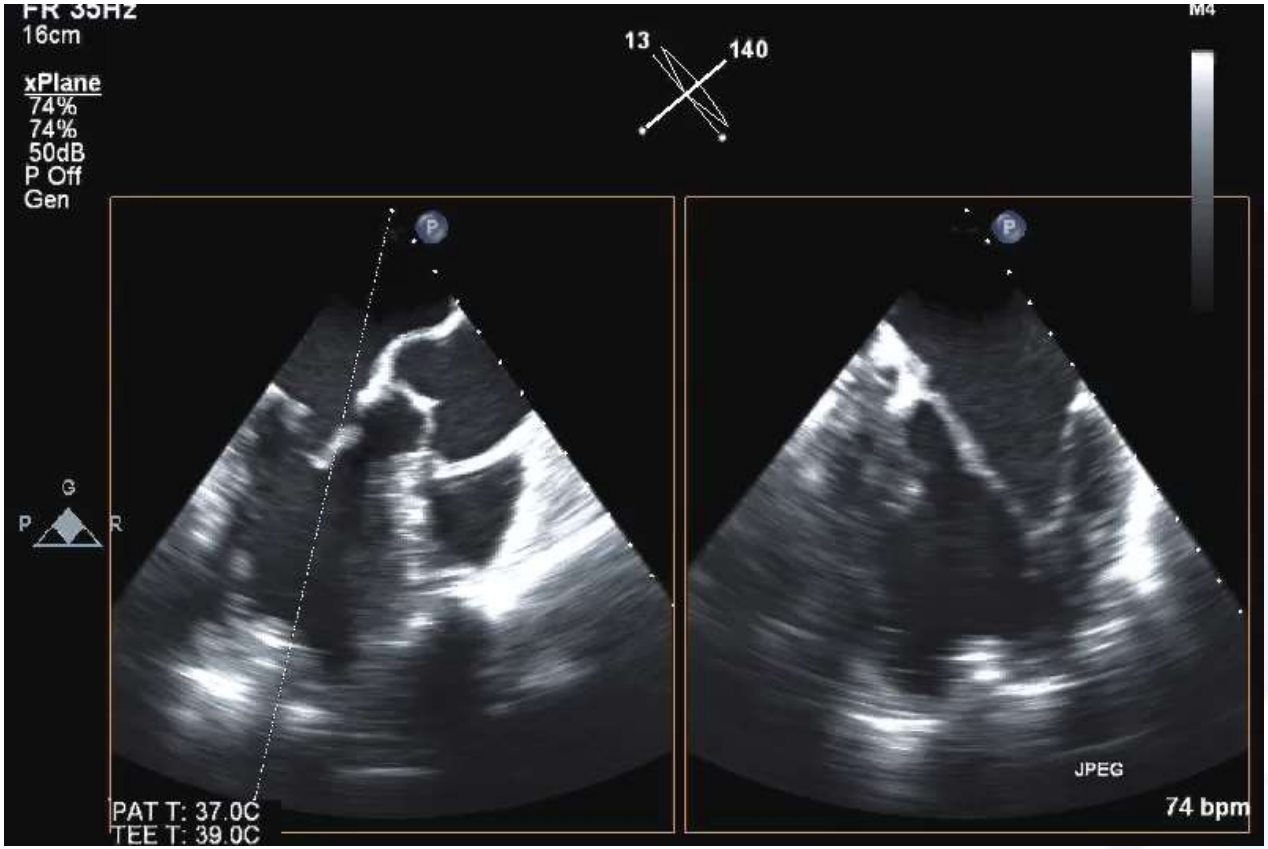
Transapical access



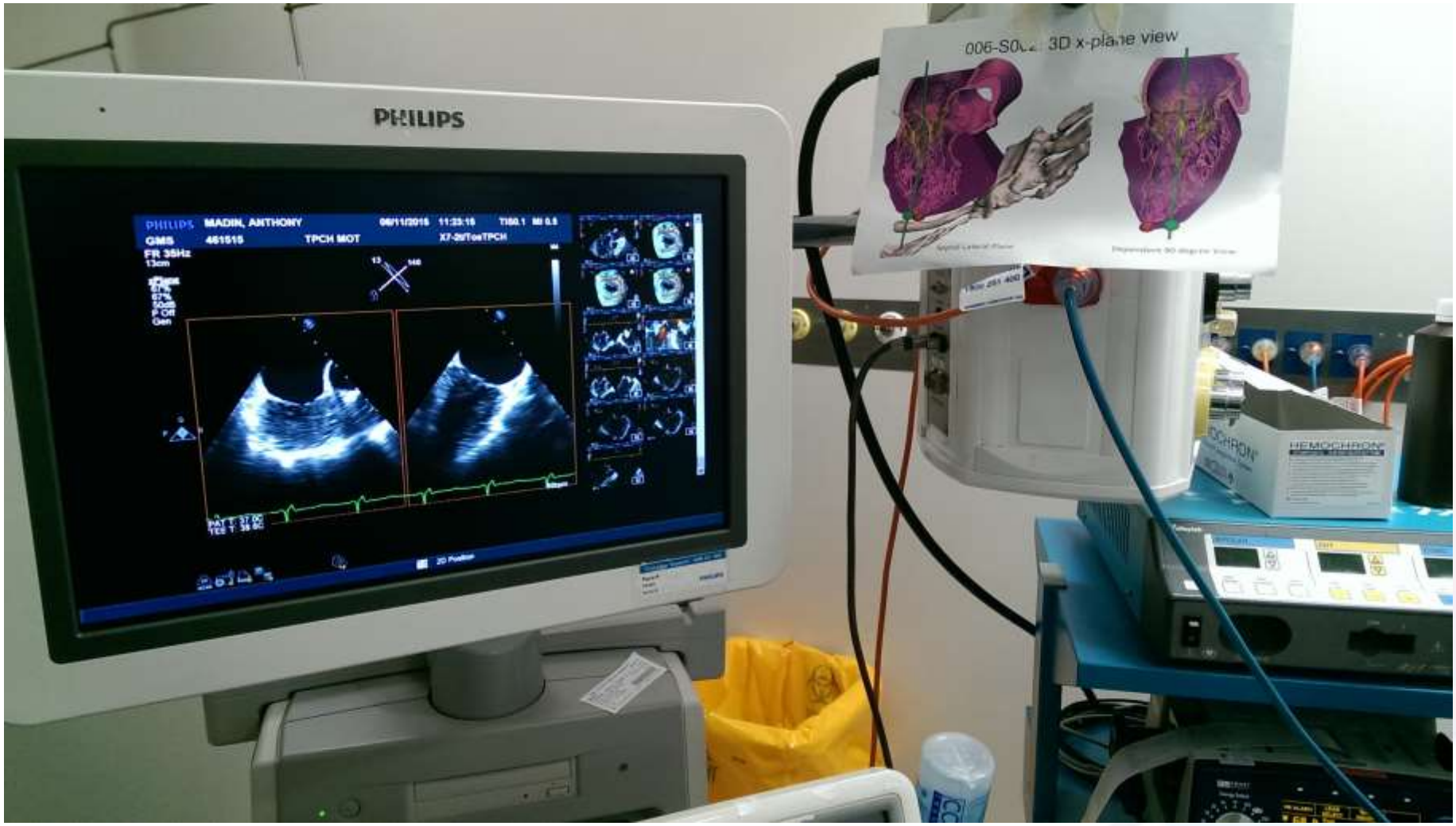
Severe Mitral Regurgitation

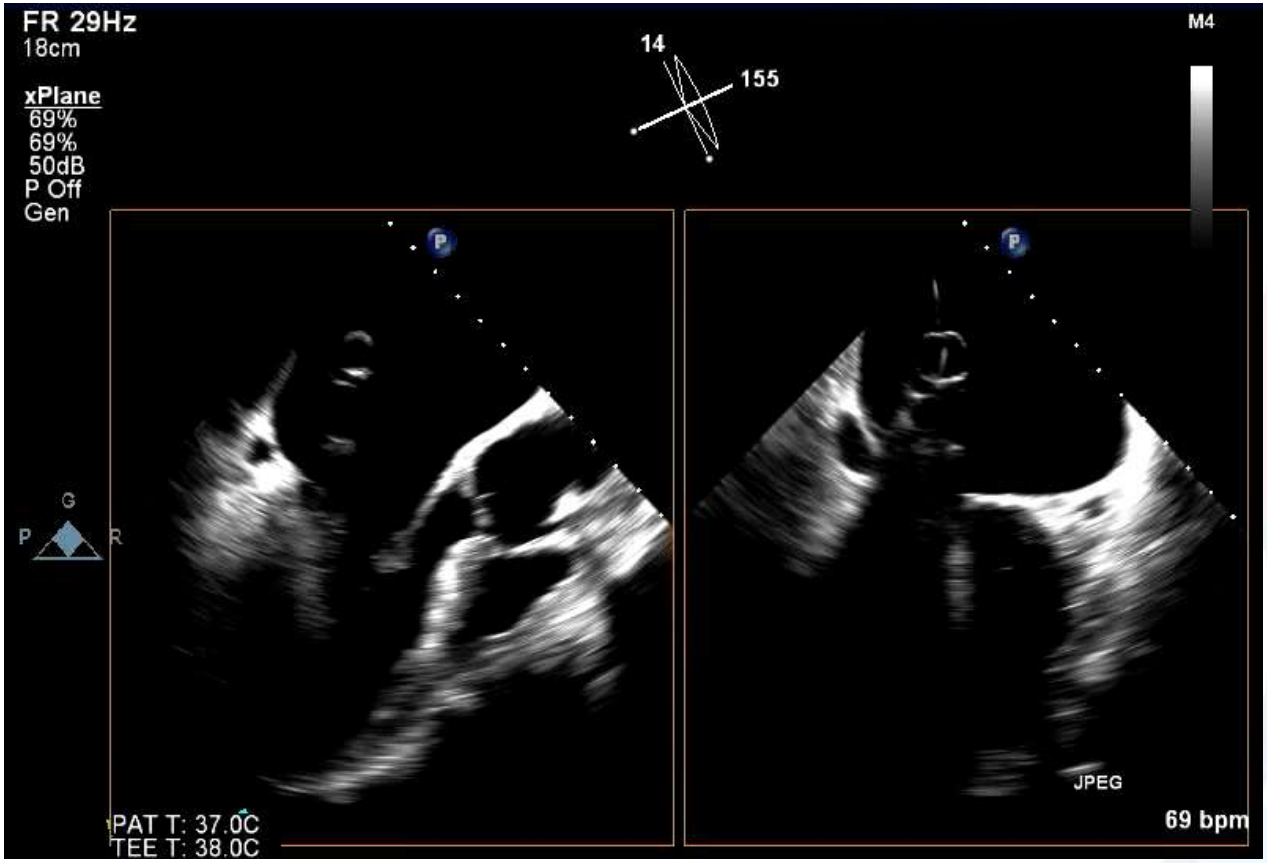




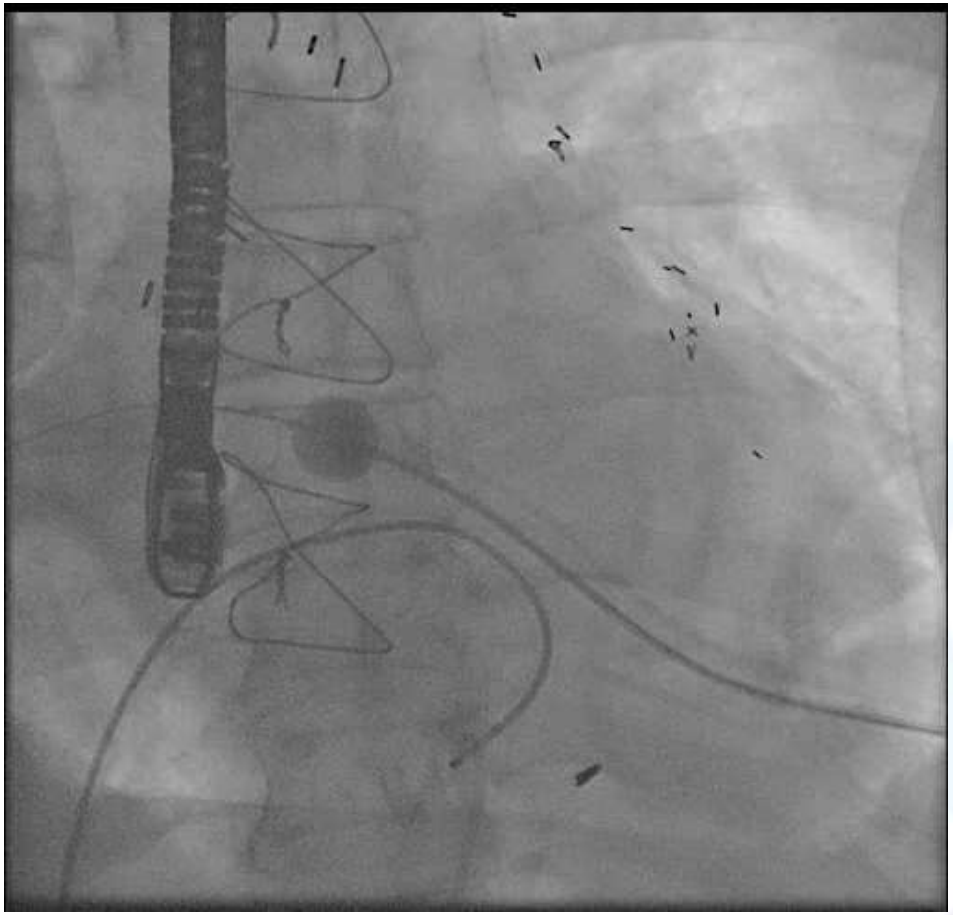

FR 35Hz
16cm
xPlane
74%
74%
50dB
P Off
Gen
13
140
M4
G
P
R
PAT T: 37.0C
TEE T: 39.0C
JPEG
74 bpm

Hi –tech planning

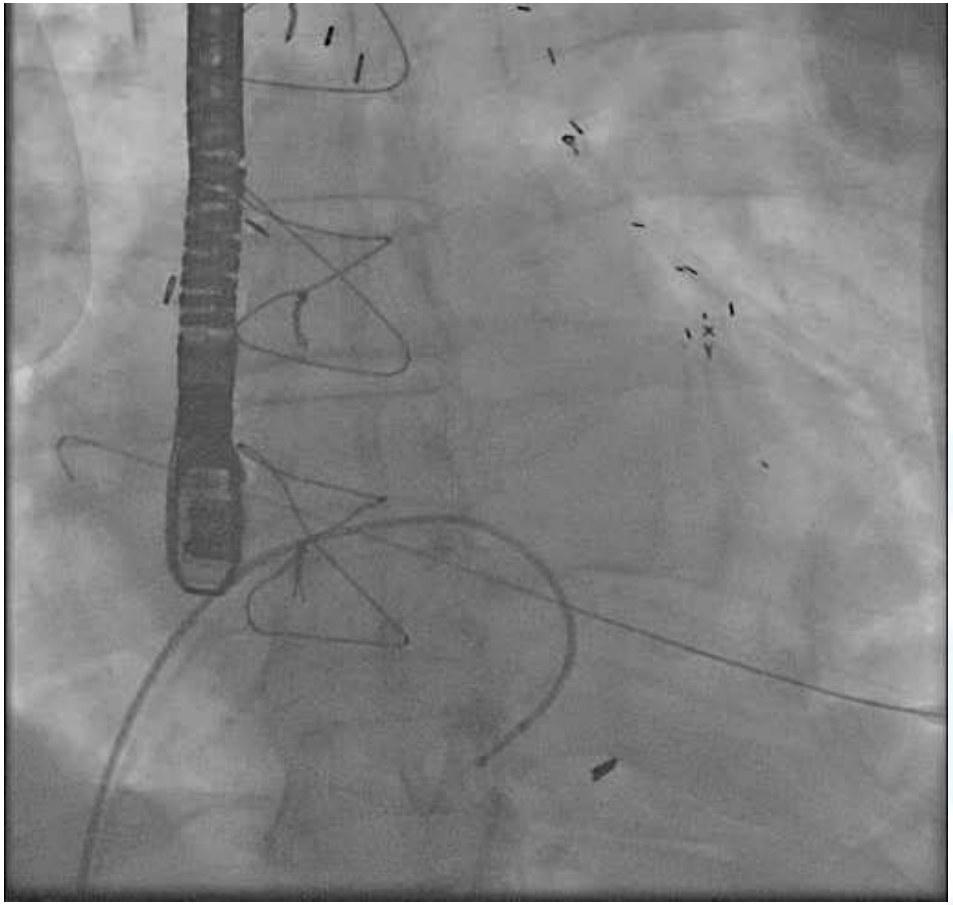



FR 29Hz
18cm
xPlane
69%
69%
50dB
P Off
Gen
14
155
M4
G
P
R
PAT T: 37.0C
TEE T: 38.0C
JPEG
69 bpm

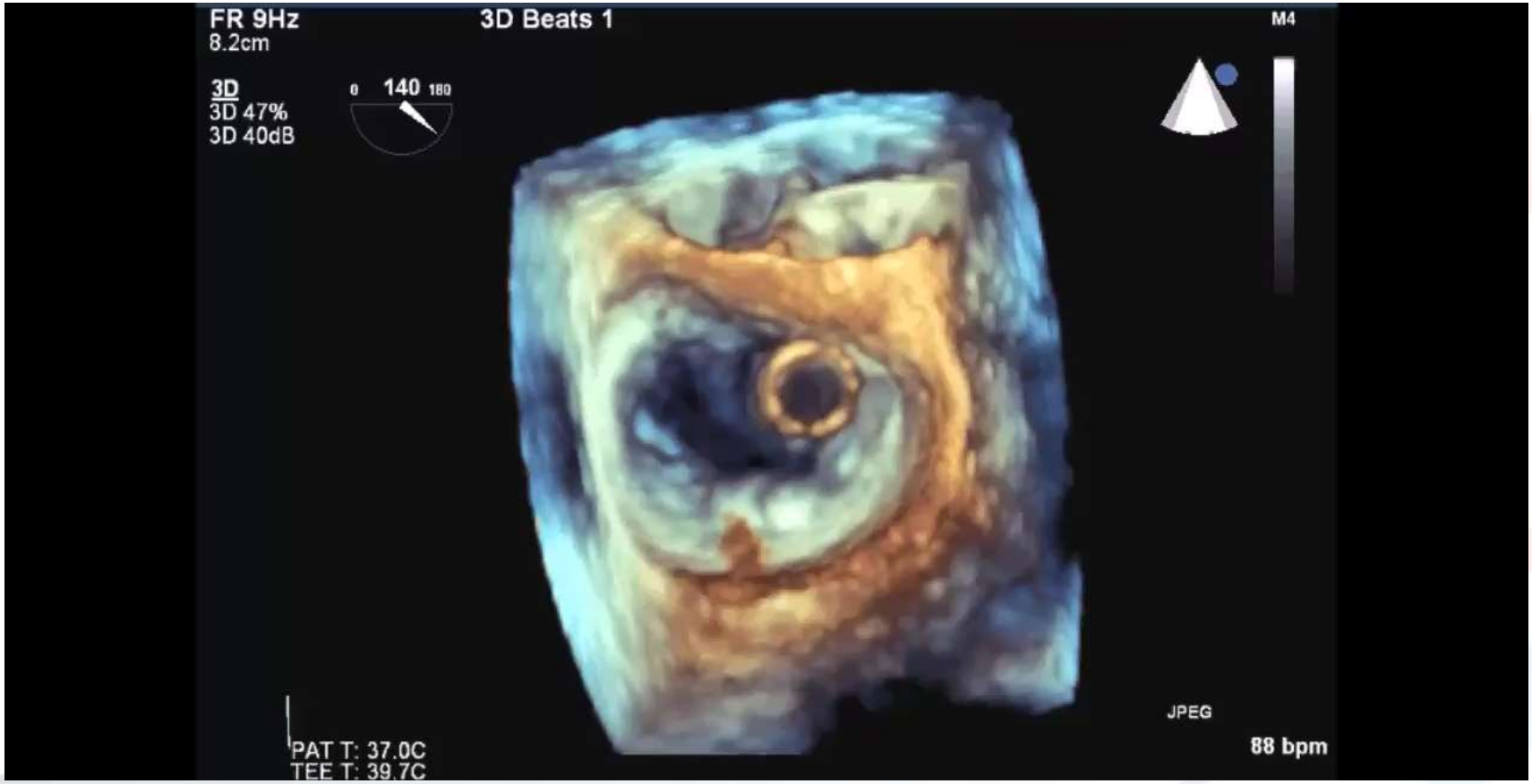
Introduction of wire to pulmonary vein



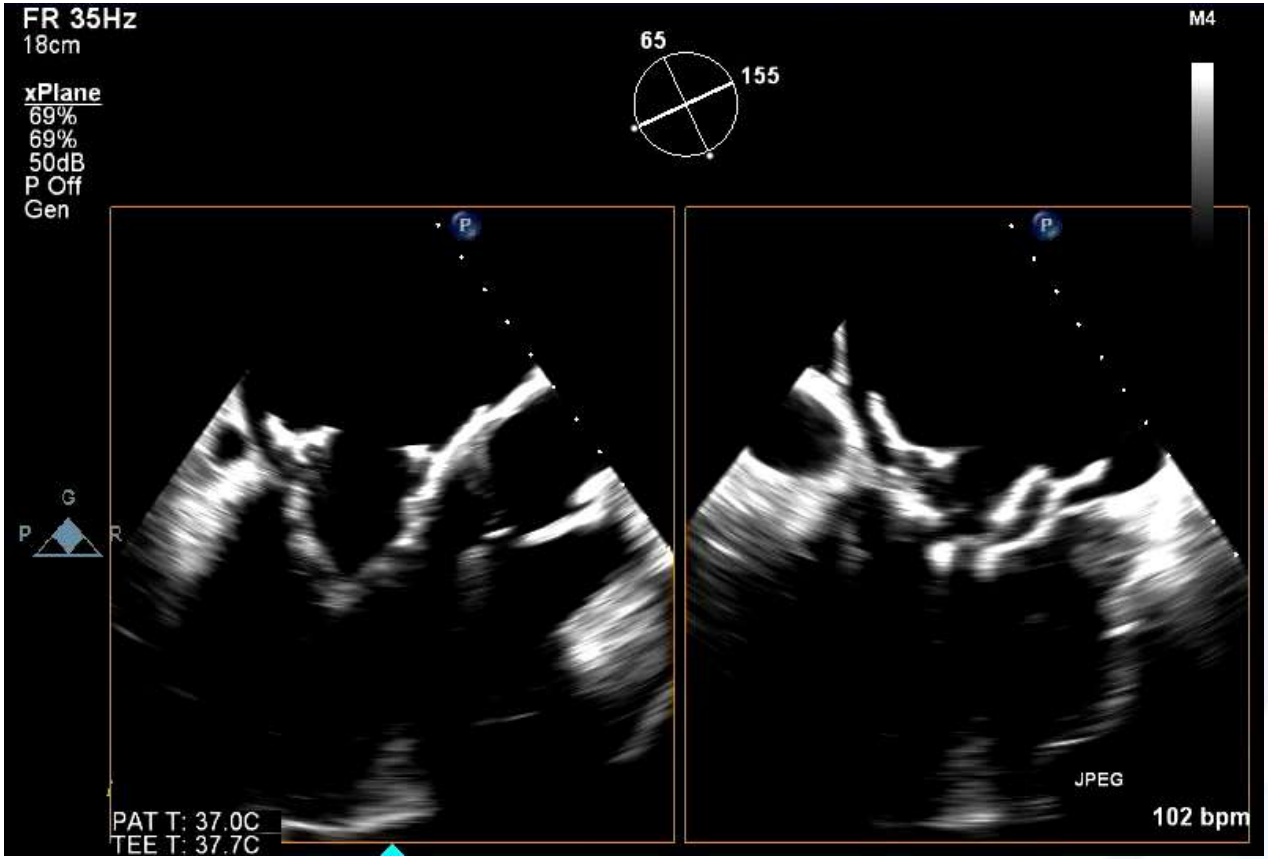
Introduction of sheath and valve



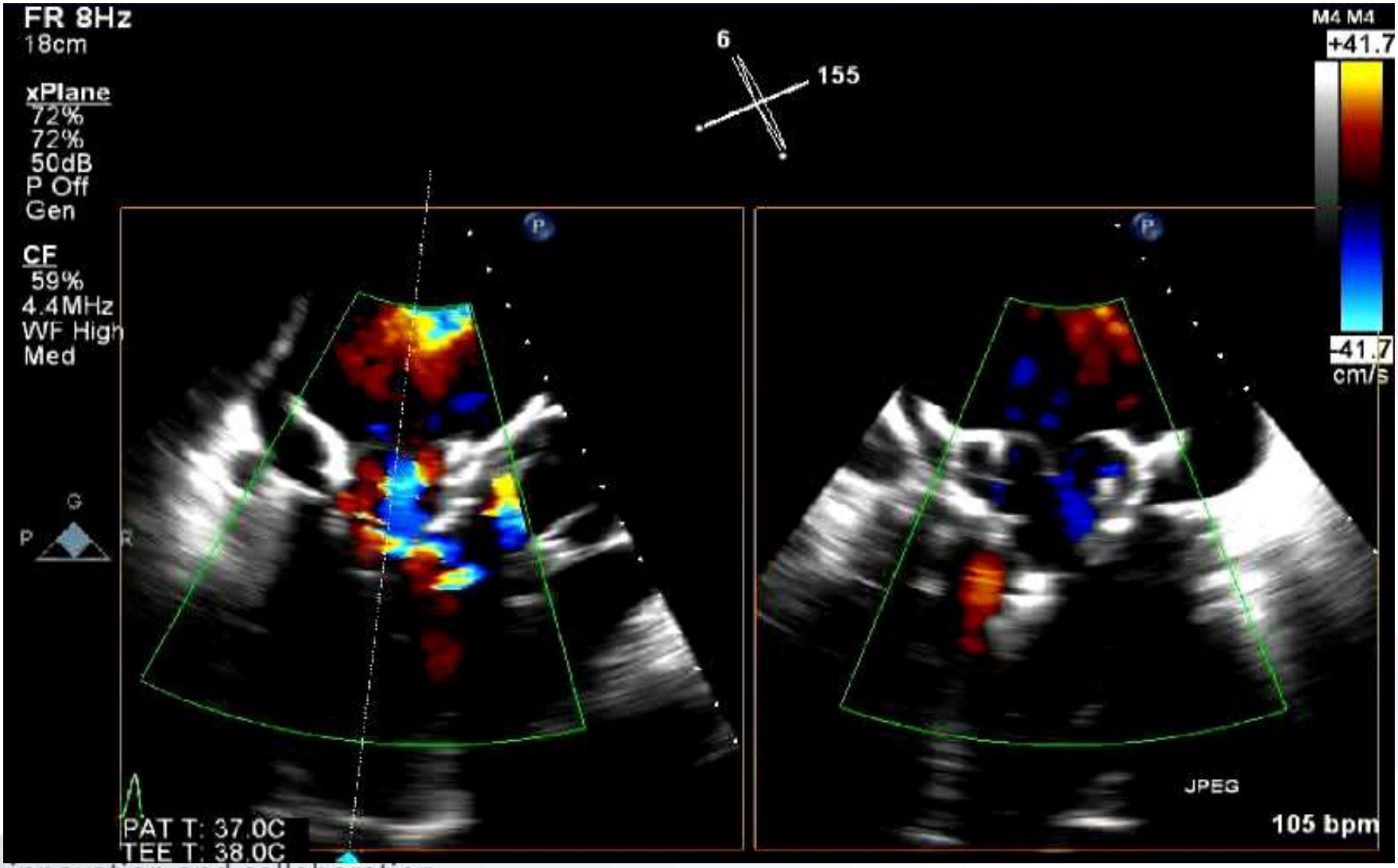
Introduction on 3 D Echo- Case 1



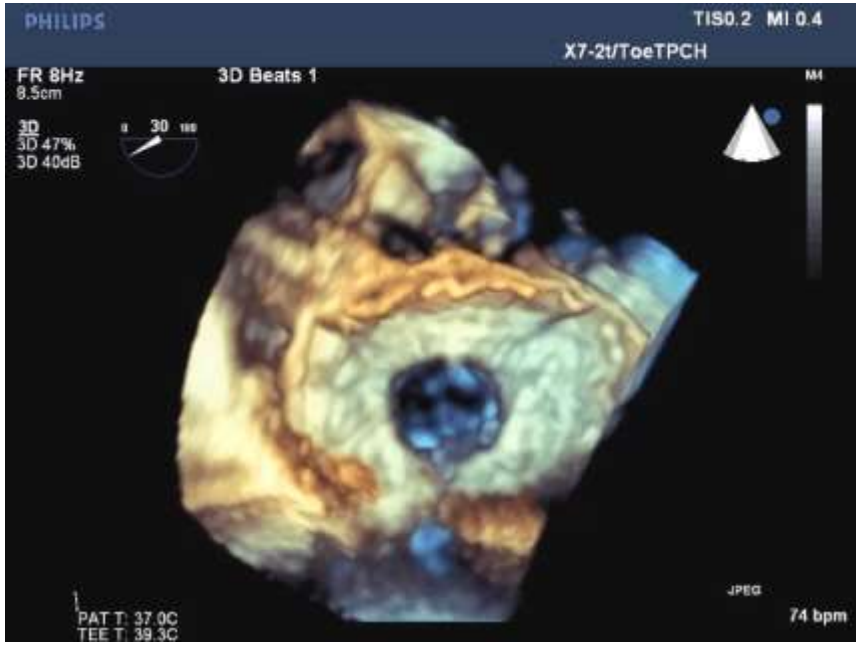
Deploying Valve

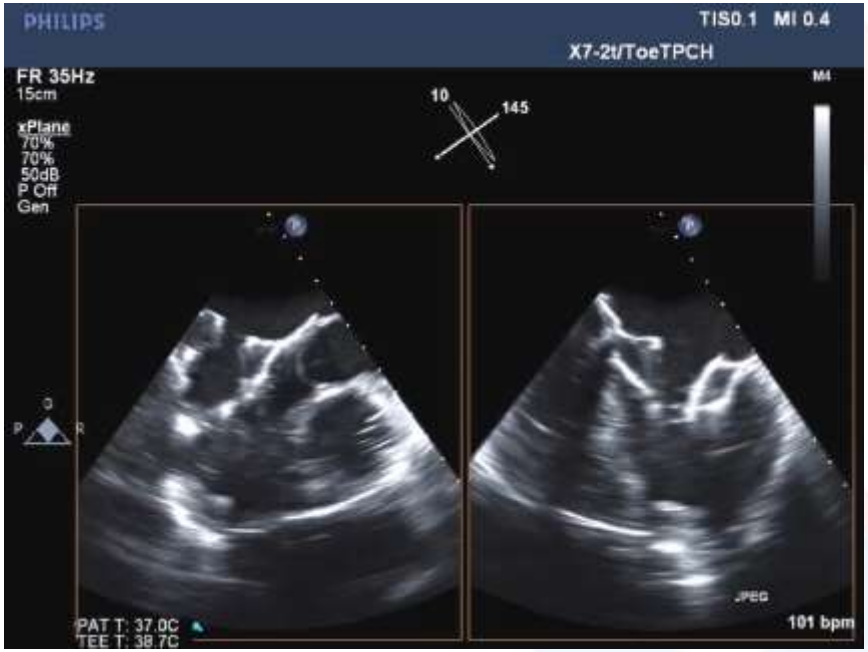


Seating valve



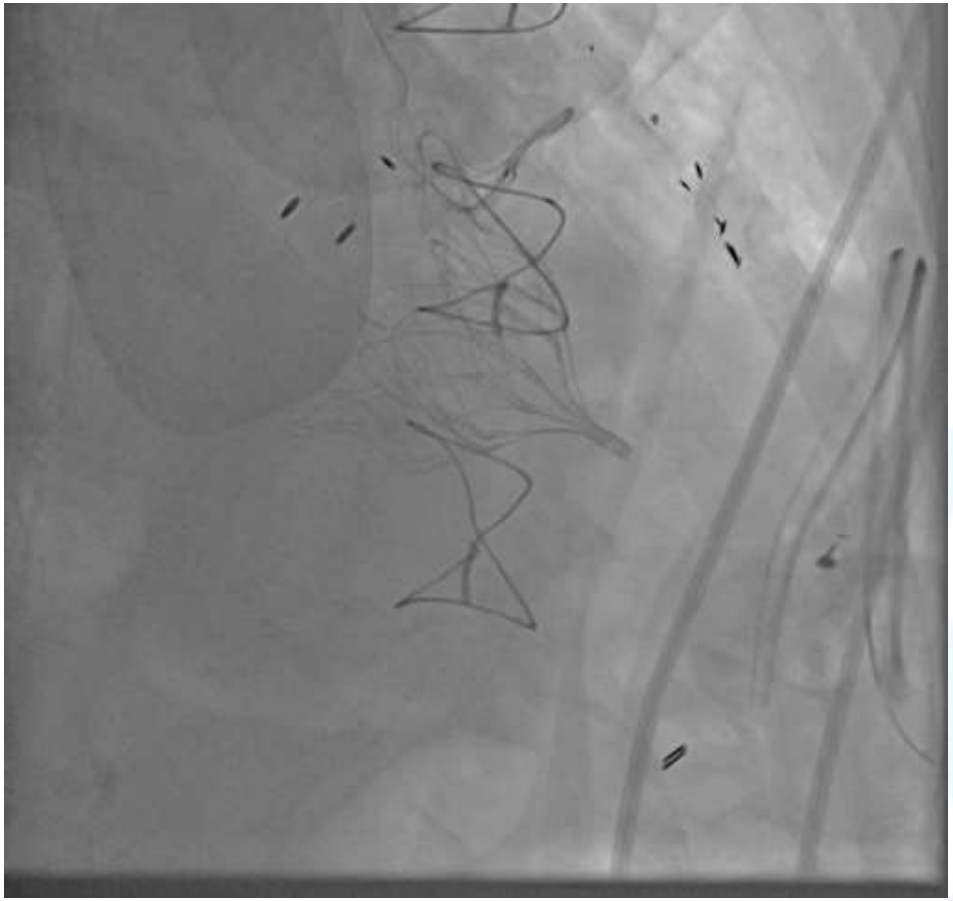
Positioning





Post tensioning

Final result



Baseline Characteristics (n=23)

Age	**76.9±9.0**
Men – no. %	21 (91.3%)
Etiology of MR – no. %	
Primary	3 (13.0)
Secondary	16 (69.6)
Mixed	4 (17.4)
NYHA functional class	
II	11 (47.8)
III	12 (52.2)
IV	0 (0.0)
Diabetes mellitus – no. %	9 (39.1)
Prior myocardial infarction – no. %	12 (52.2)
Prior percutaneous revascularization – no. %	6 (26.1)
Prior coronary artery bypass surgery	10 (43.5)
Prior stroke	1 (4.3)
Chronic kidney disease (eGFR <60 ml/min)	13 (56.5)
COPD	7 (30.4)
Atrial fibrillation	13 (56.5)
CRT-D	9 (39.1)
Body mass index (kg/m^2)	26.4±5.6
Left ventricular ejection fraction <50% - no. %	14 (63.6)
STS-PROM	9.5±12.8
EuroScore II	6.3±5.1

Outcomes at 30 days

Death – no. (%)	**1 (4.3)**
Stroke (disabling or non-disabling) – no. (%)	0 (0.0)
Myocardial infarction – no. (%)	0 (0.0)
Bleeding (BARC classification) – no. %	
Type 2	2 (8.7)
Type 3	0 (0.0)
Type 4	1 (4.3)
Type 5	0 (0.0)
New onset atrial fibrillation – no. (%)	0 (0.0)
Transient, acute renal insufficiency – no. (%)	3 (13.0)
New dialysis requirement – no. (%)	1 (4.3)
Non-cardiac bacteremia – no. (%)	2 (8.7)
Prosthetic dysfunction – no. (%)	
Thrombosis	1 (4.3)
Migration or embolization	0 (0.0)
Hemolysis	0 (0.0)
Mitral valve surgery	0 (0.0)
Rehospitalization	
Heart failure	1 (4.3)
Pleural effusion	1 (4.3)
Other (ileus)	1 (4.3)

Conclusion

- Safe feasible
- Excellent early result
- steep procedural, planning and selection learning curve