

Transcatheter Mitral Valve Implantation

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Disclosure:

John Webb

- Abbott
- Edwards Lifesciences
- Gore
- Medtronic
- Mitralign
- Orford
- St Jude Medical
- Transverse Medical
- Siemens
- Valtech
- Vivitro

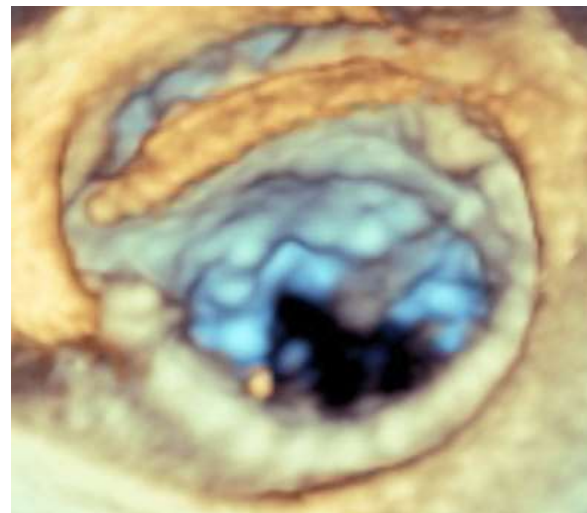
Jian Ye

Edwards Lifesciences
JC Medical Inc.

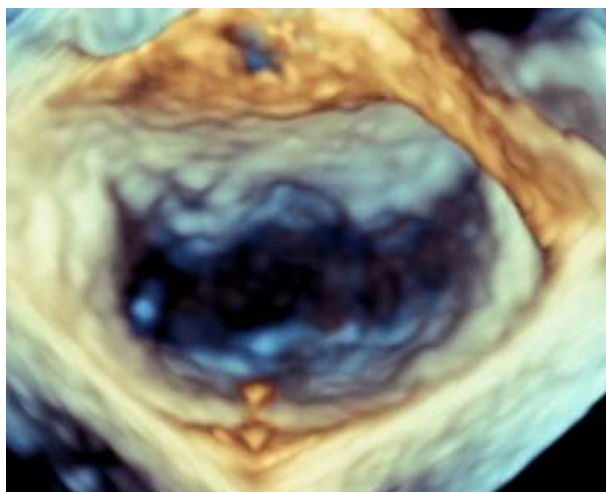
Transcatheter mitral repair & replacement



Leaflet repair: Mitraclip



Annuloplasty: Cardioband



Chordal repair: Neochord



TMVI: 5 in trials now

Transcatheter Mitral Valves in Humans



Edwards Fortis



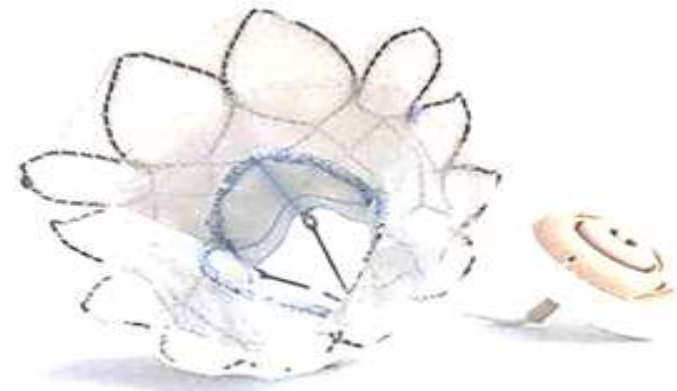
Neovasc Tiara



Edwards CardiAQ

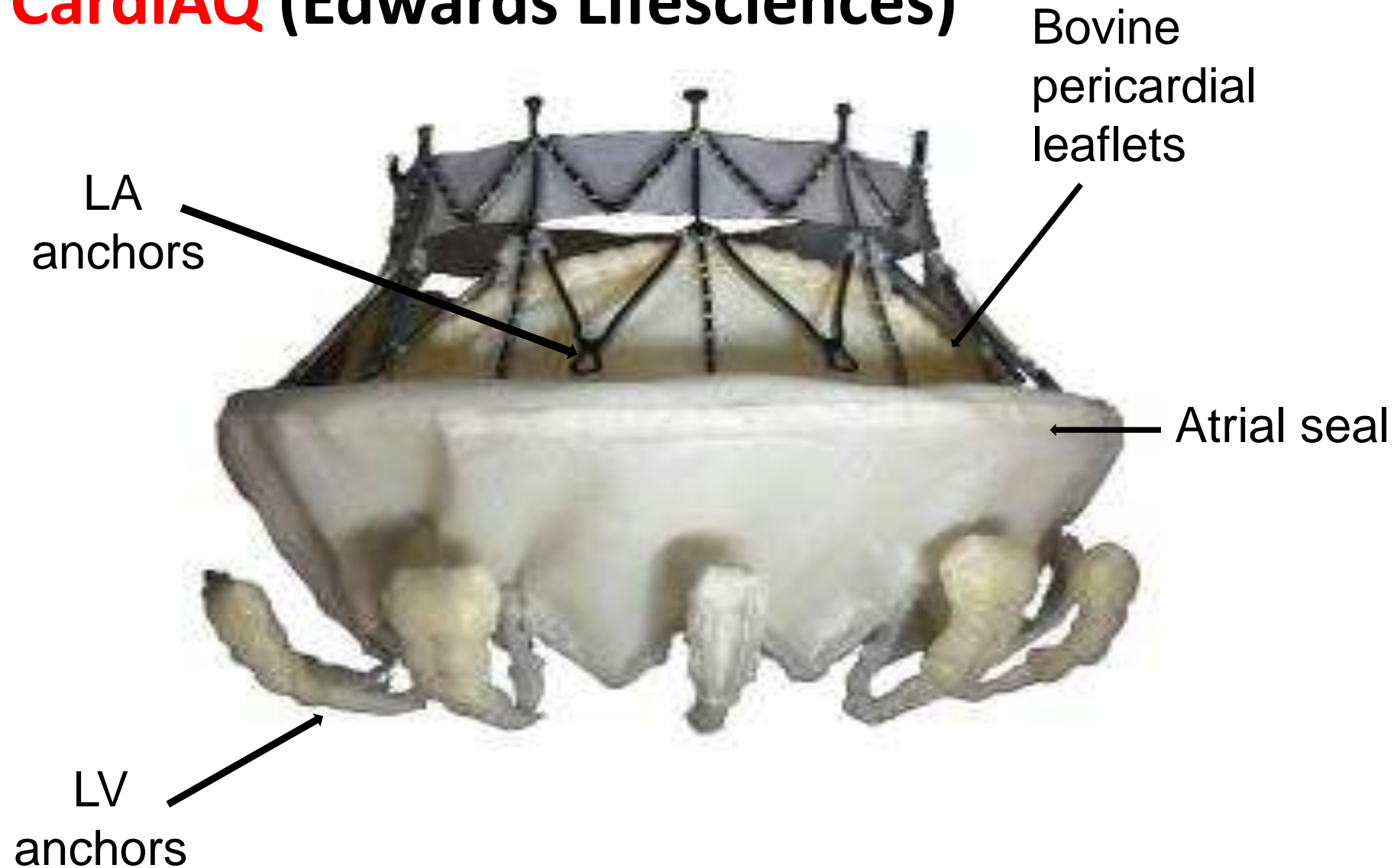


Medtronic Intrepid



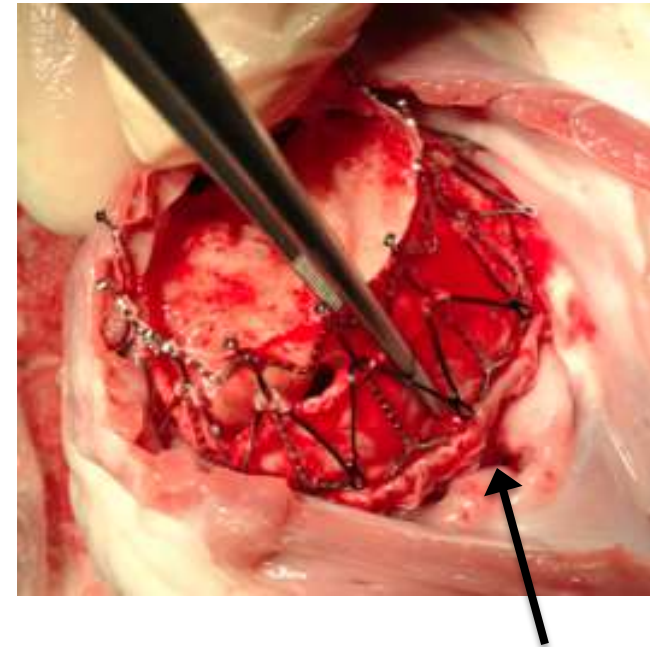
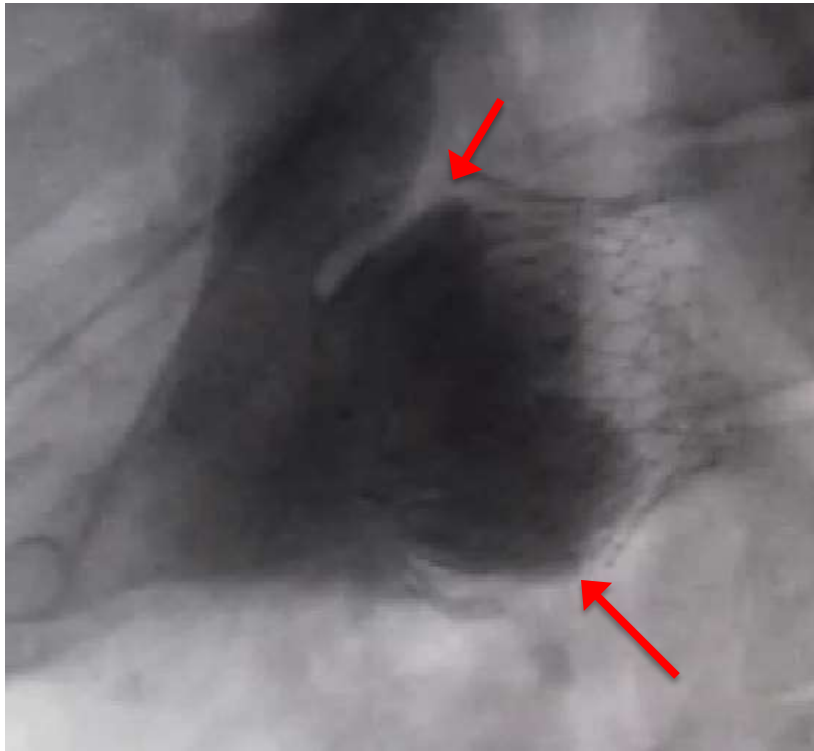
Abbott Tendyne

CardiAQ (Edwards Lifesciences)

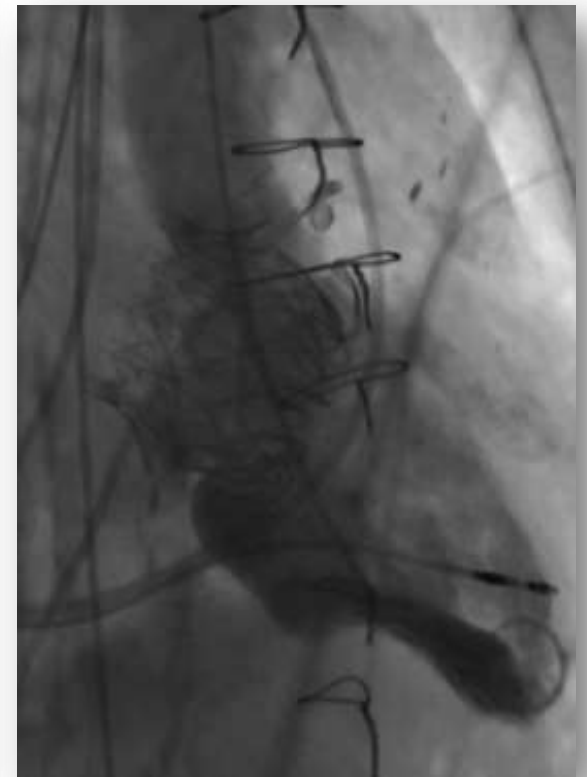


CardiAQ

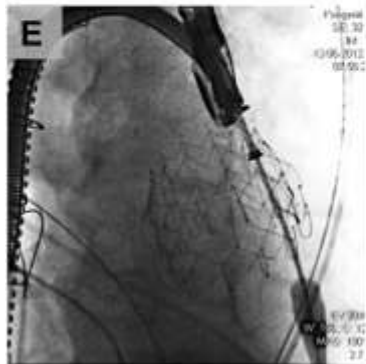
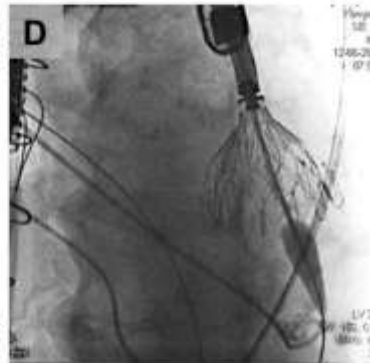
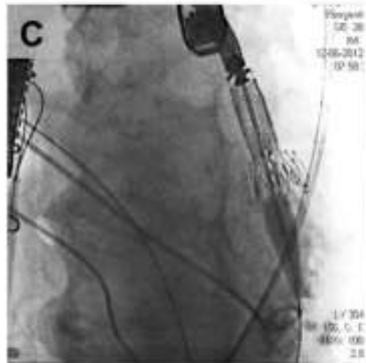
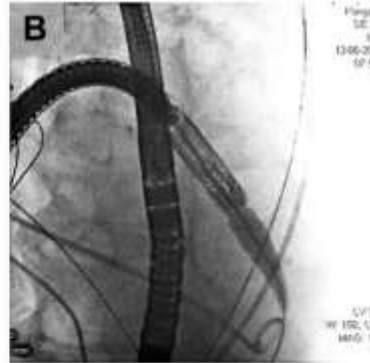
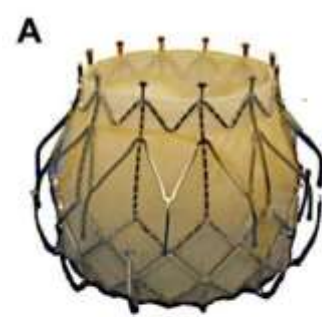
Intra-annular Sealing Skirt to prevent PVL



CardiAQ: transapical implantation



CardiAQ



June 12, 2012

1st TMVI

Copenhagen

Transseptal

Fem-fem bypass

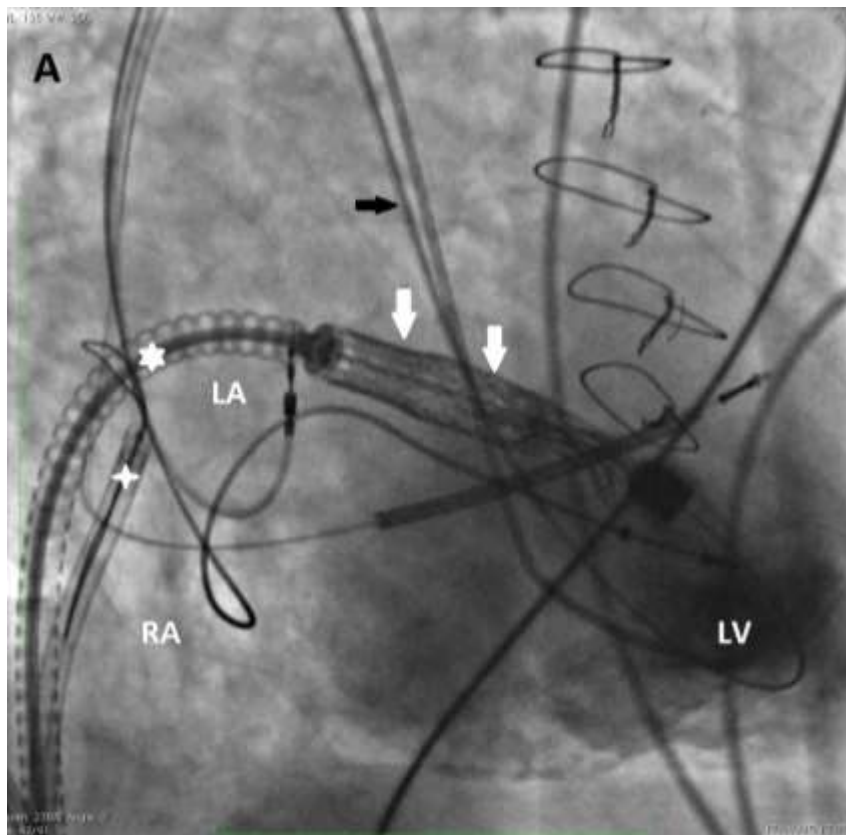
Successful

Multiorgan failure

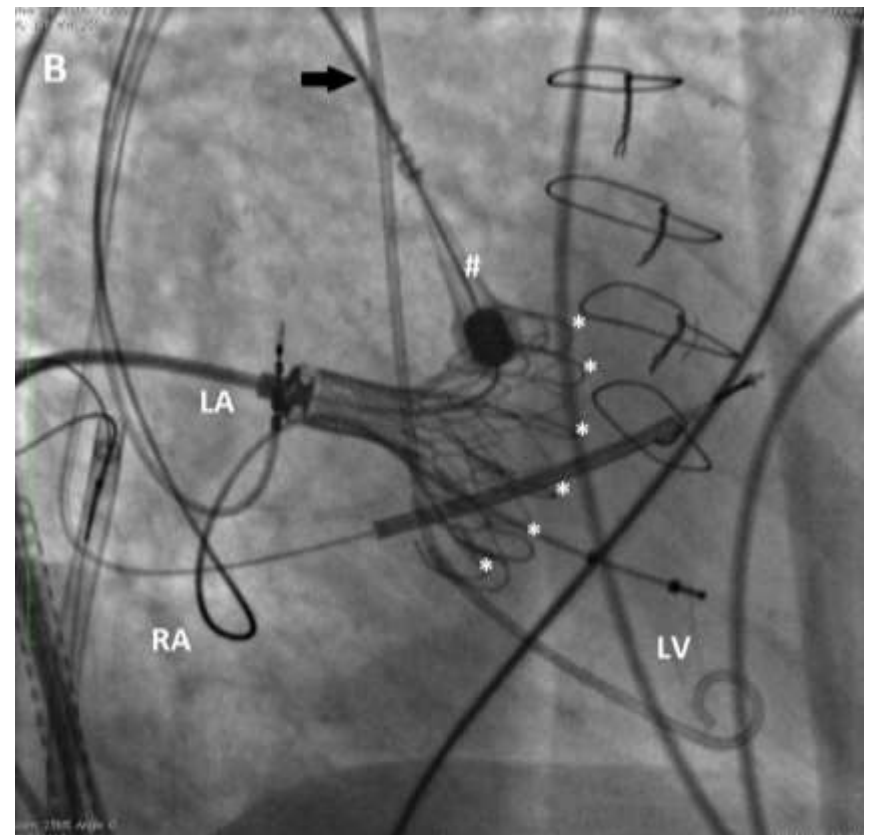
Died day #3

CardiAQ transseptal implantation

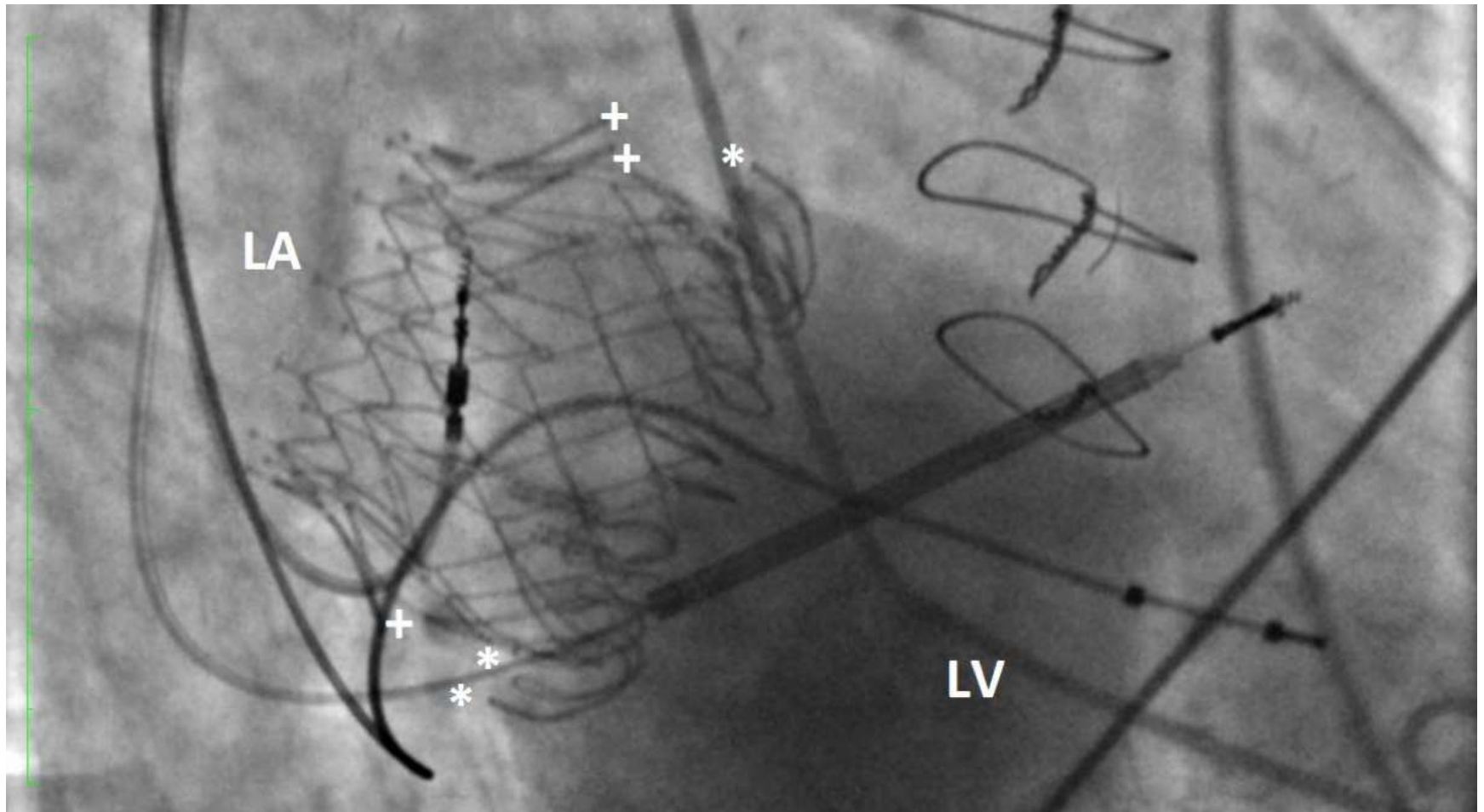
Transseptal access



AV wire loop for orientation



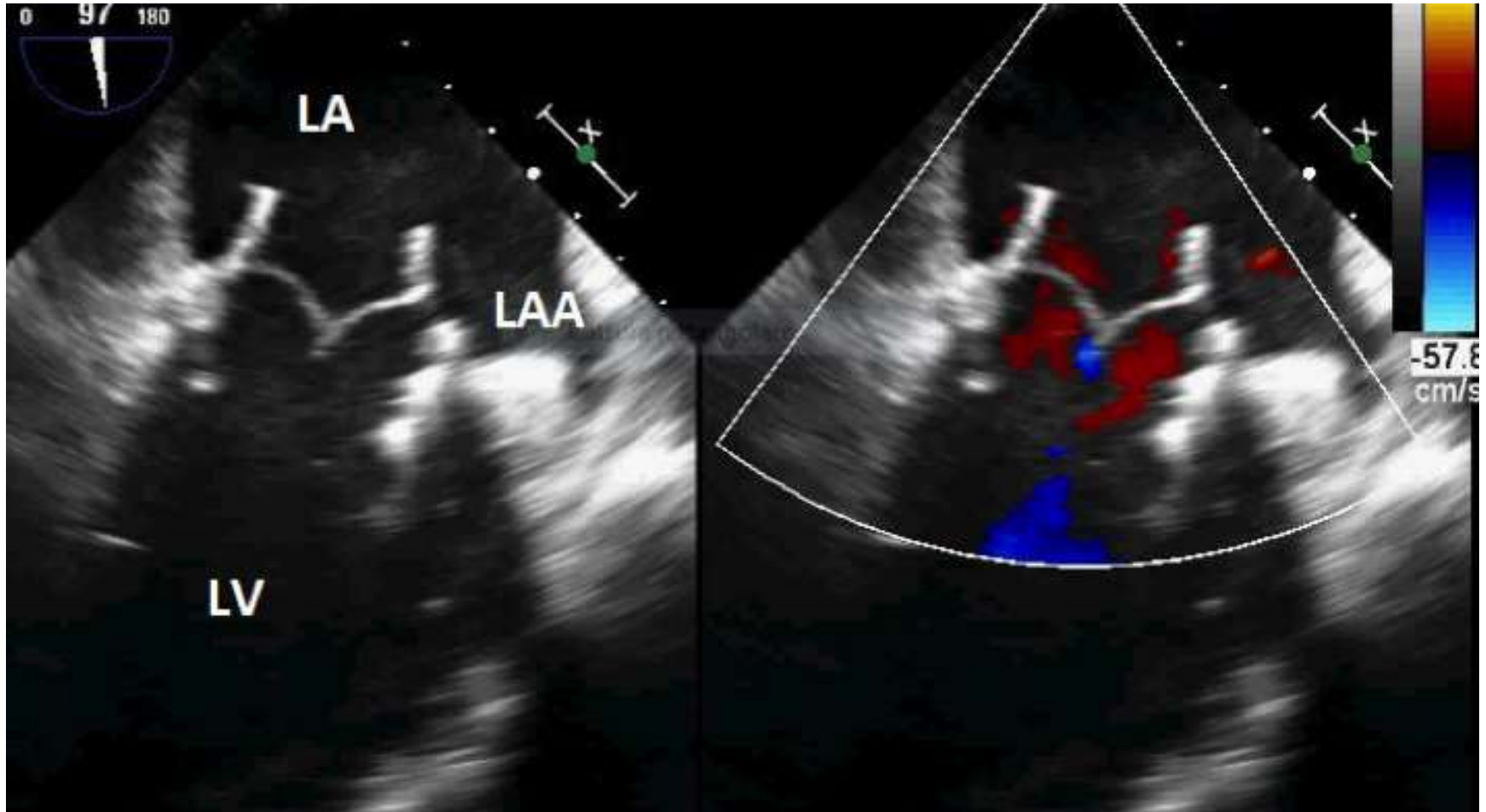
CardiAQ: transseptal implantation



CardiAQ

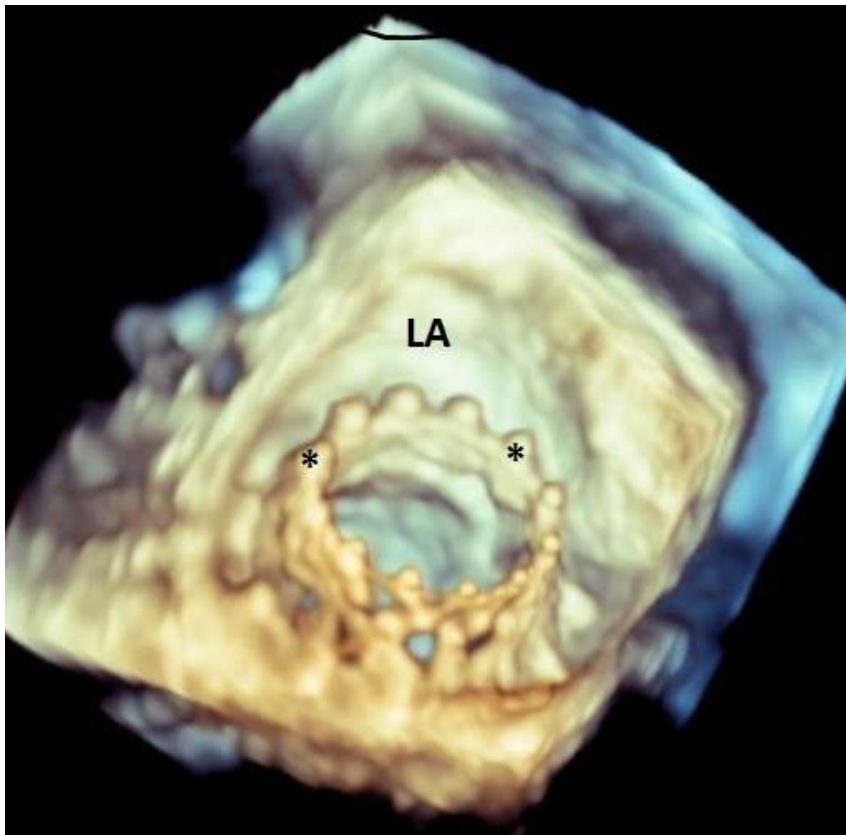
Valve displaced into atrium

No leak, no LVOT obstruction

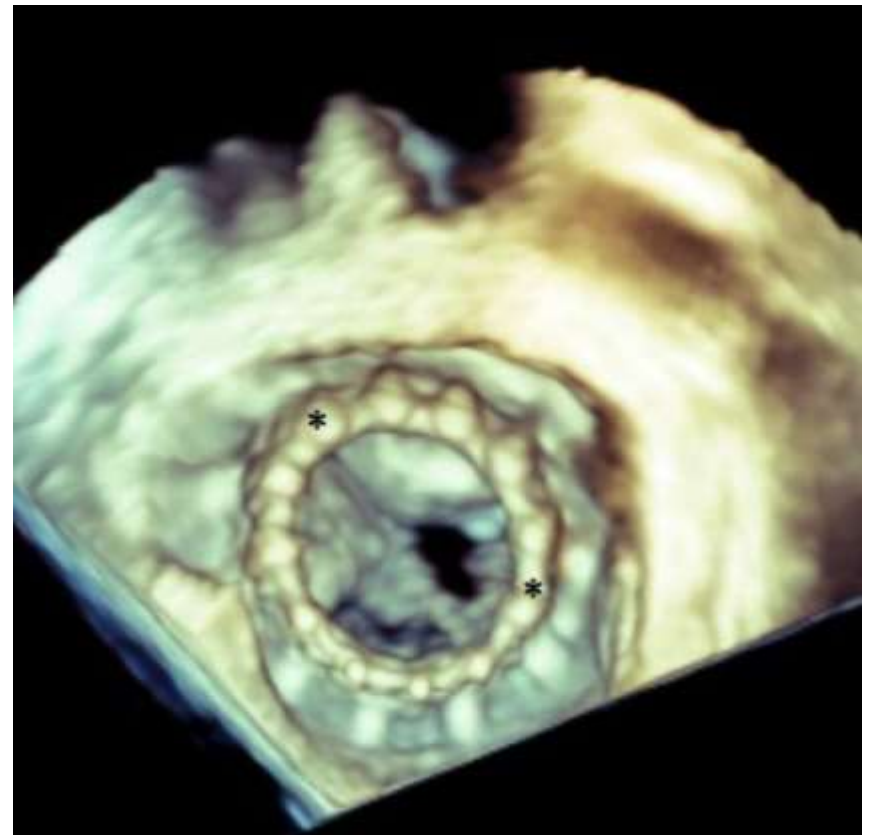


CardiAQ

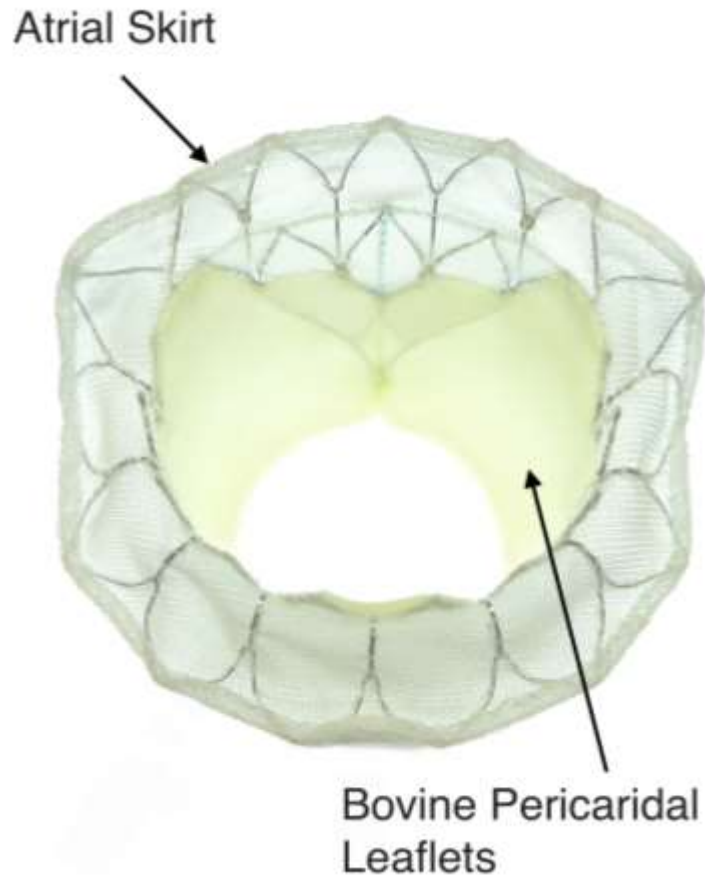
Atrial view



Ventricular view

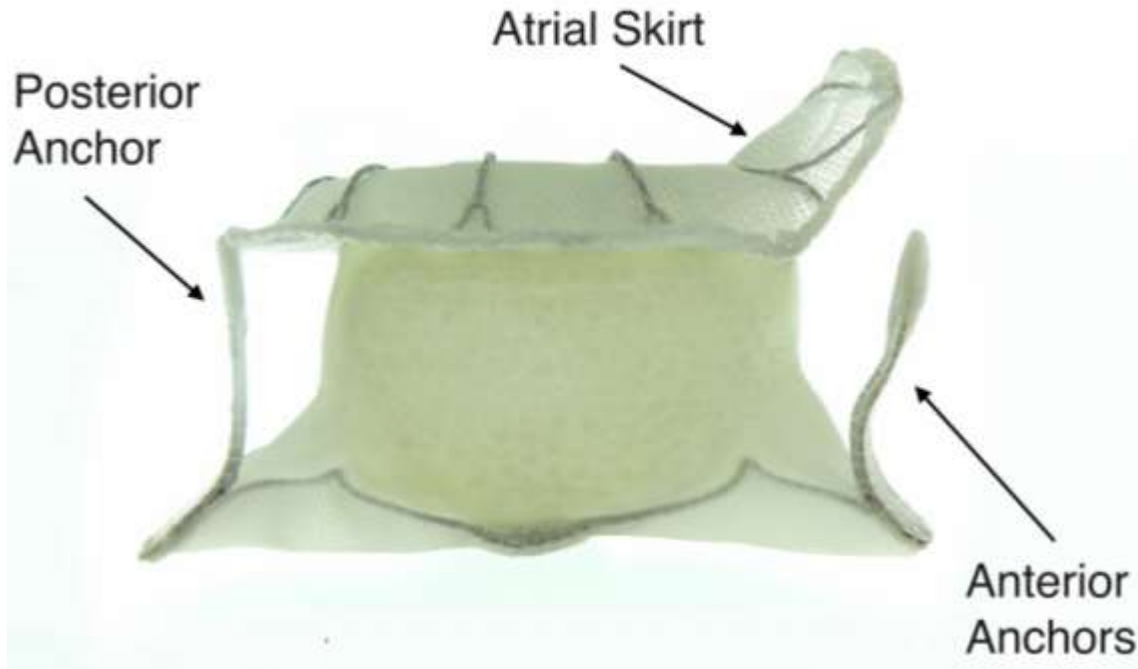


Tiara Mitral Prosthesis



- Nitinol self-expanding frame
- D-shaped trileaflet valve
- Bovine leaflets x3
- 35 and 40mm sizes

Tiara Transcatheter Mitral Valve



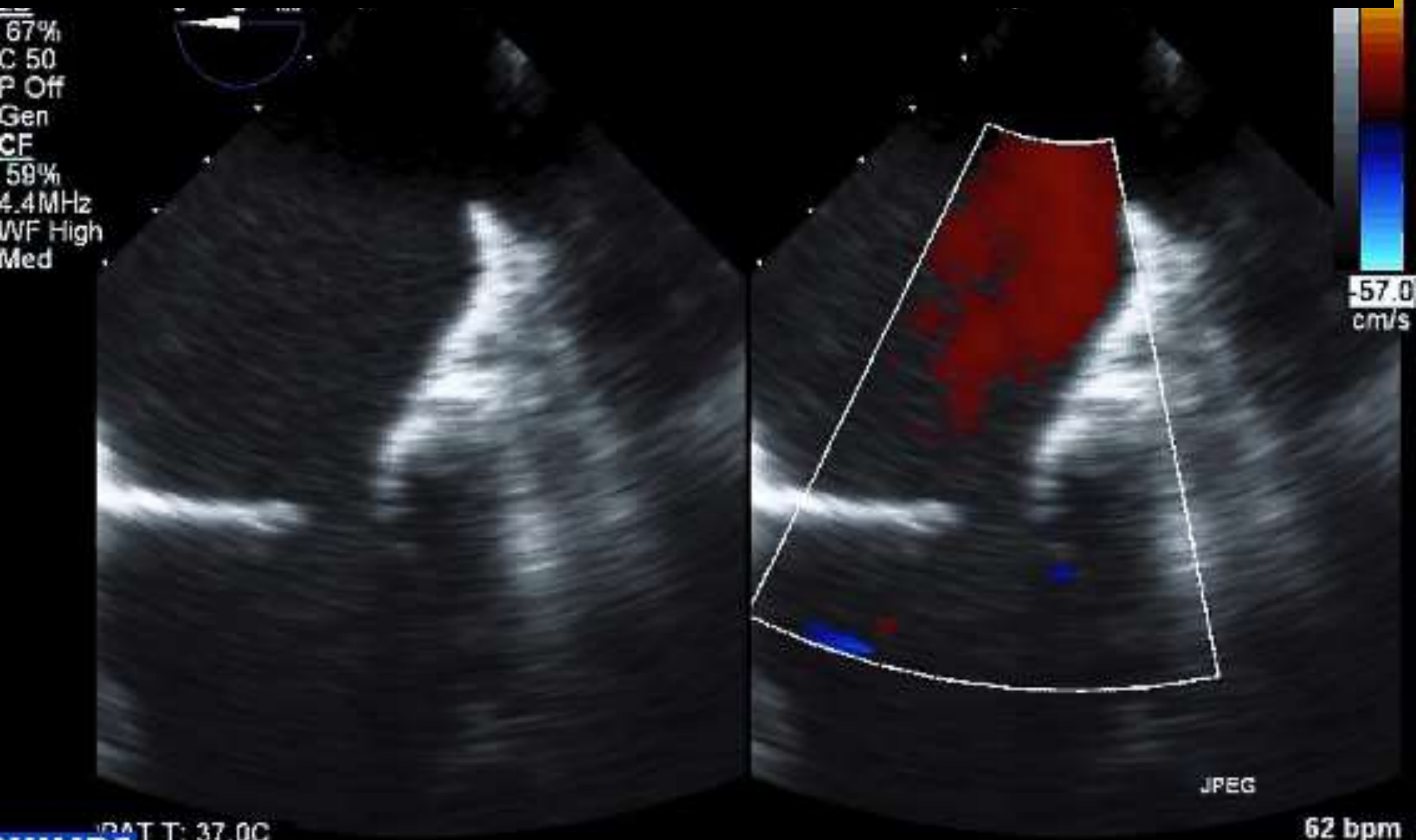
- Ventricular anchors
- Fixation
 - fibrous trigones
 - posterior annulus
- Captures the anterior and posterior leaflets

Clinical Case

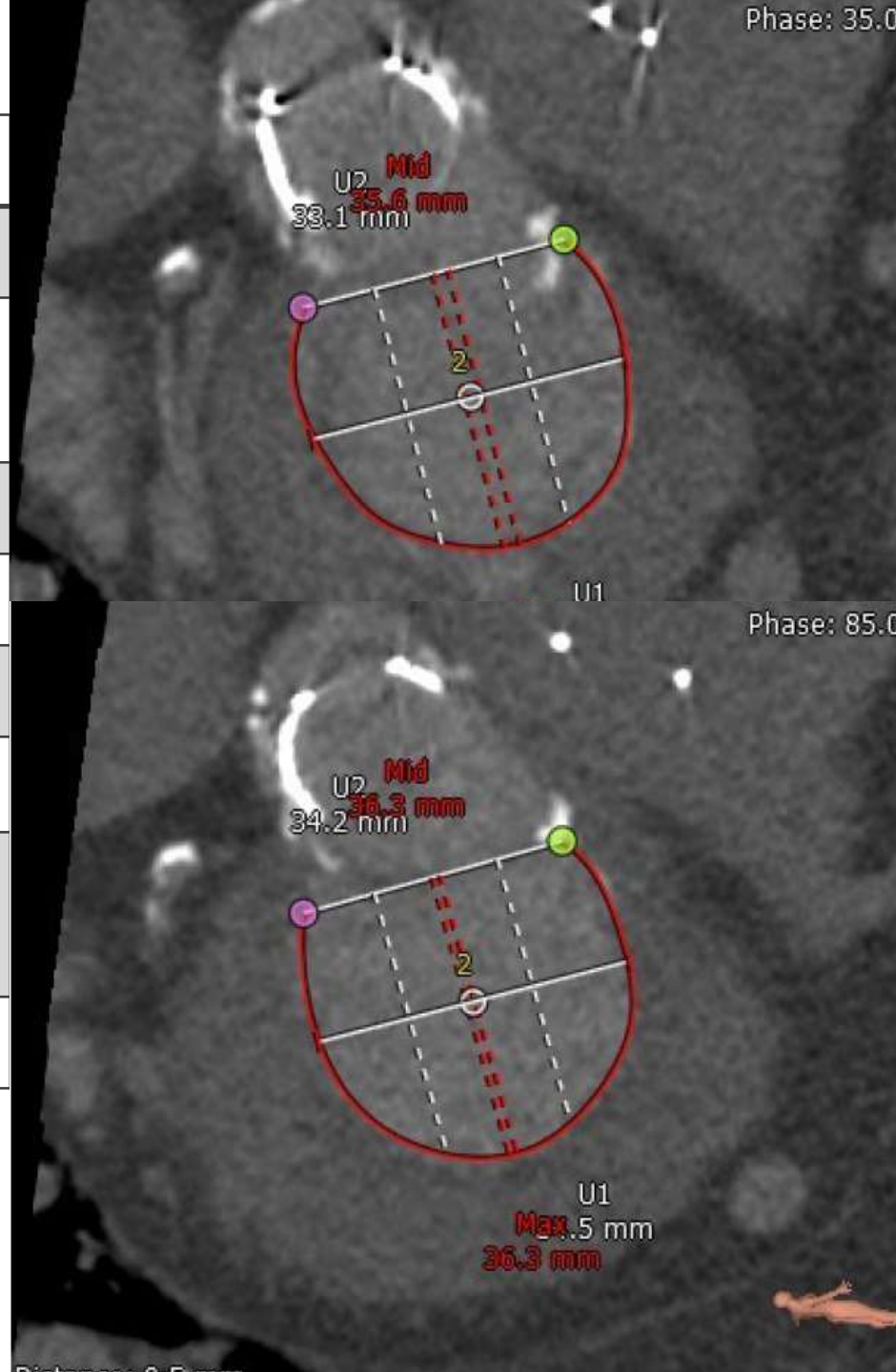
Age/Gender	79 year old male
History	<ul style="list-style-type: none">• 2009 – CABG LIMA to LAD and AVR with 23mm Perimount pericardial valve• PCI 2004 LAD, 2013 RCA• NSTEMI 2015, PCI LM• NYHA III with severe MR• Chronic A.fib• VVIR pacemaker• HTN, dyslipemic• STS – 8.3% EuroScore II – 8.7%
Significant Comorbidities	<ul style="list-style-type: none">• Mild to mod COPD• Moderate CRI (eGFR 45)



- Severe MR LVEF ~35%
- Posterior leaflet tethering and markedly eccentric MR
 - EROA – 0.59 cm²



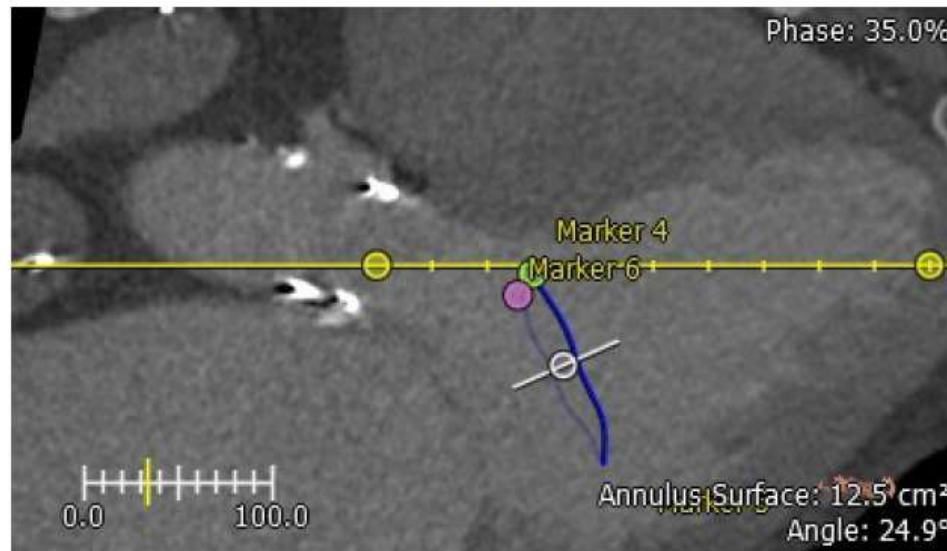
CT Variable	Results	
	Systole	Diastole
Annulus Circumference	130 mm	130 mm
Annulus Area	12.5cm ²	12.5cm ²
A-P Distance	35.7mm	36.3mm
C-C Distance	40.6mm	40.8mm
Posterior Shelf	6.6 mm	8.6 mm
Mitral Annular Calcification	Mild at A3	
Atrial Height	89.9 mm	



Neo LVOT Area = 2.11 cm²

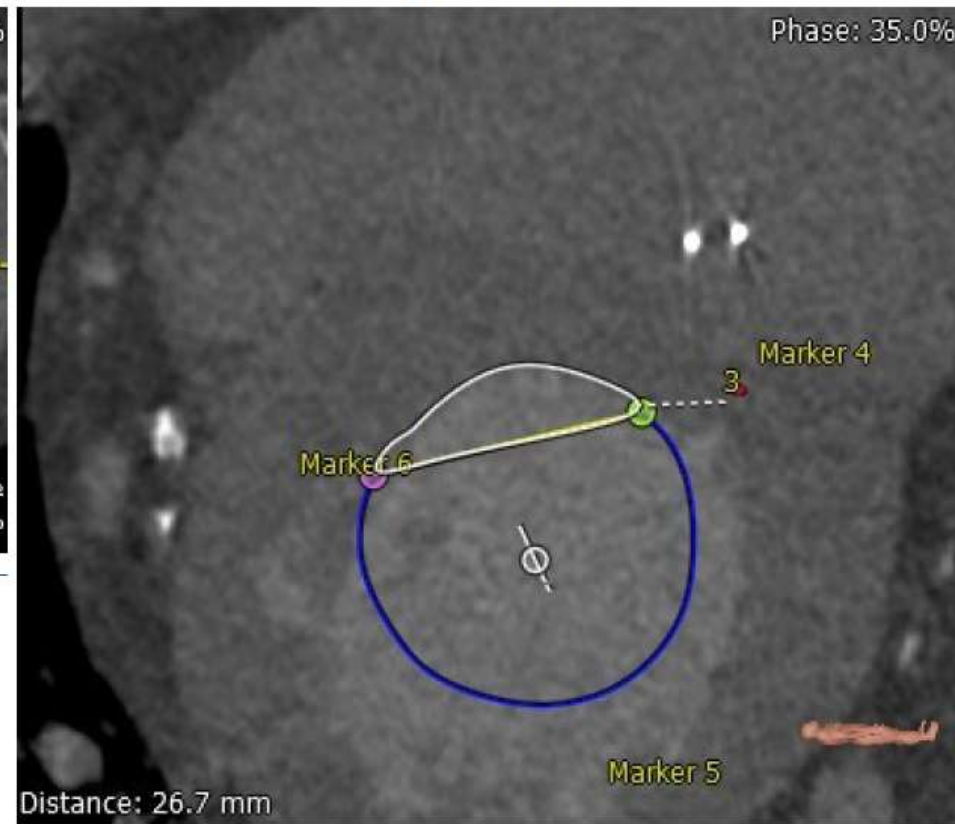
Neo-LVOT End-Systole

Phase: 35.0%



Neo-LVOT End-Systole

Phase: 35.0%

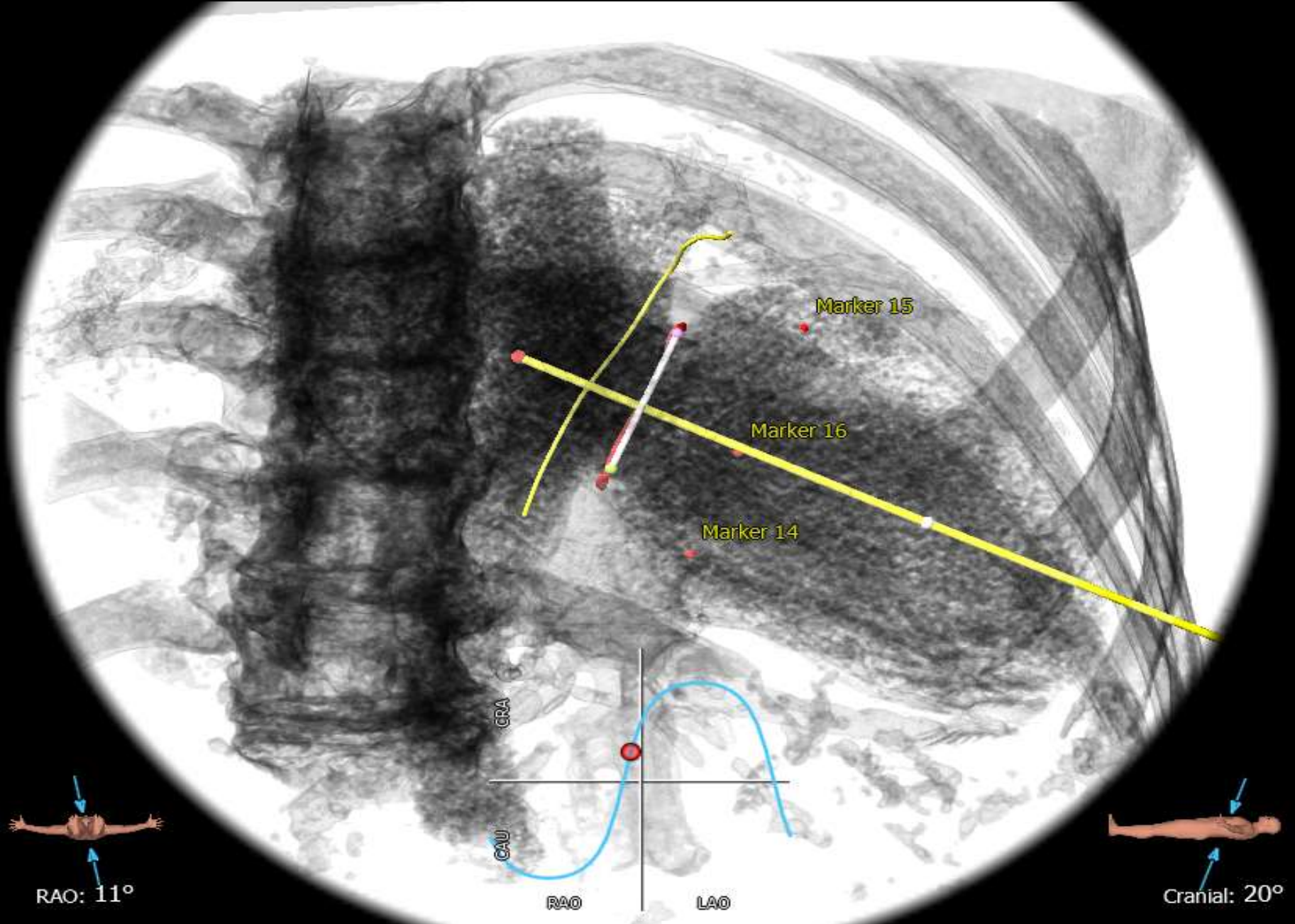


ID	Type	Label	Value
3	Polygon Area		211.3 mm ²

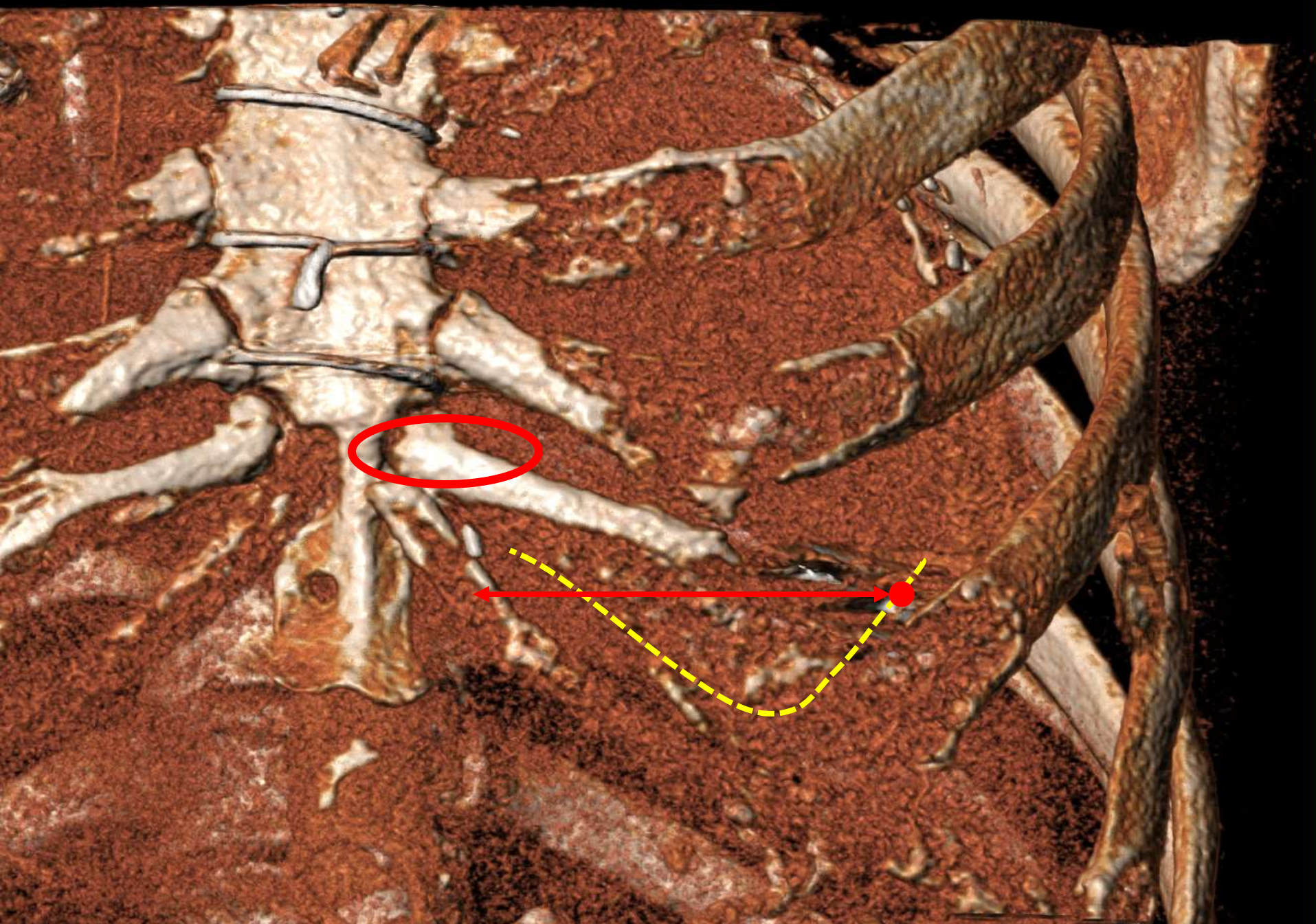
3D printing of CT (different patient)



Projected C-arm angulation

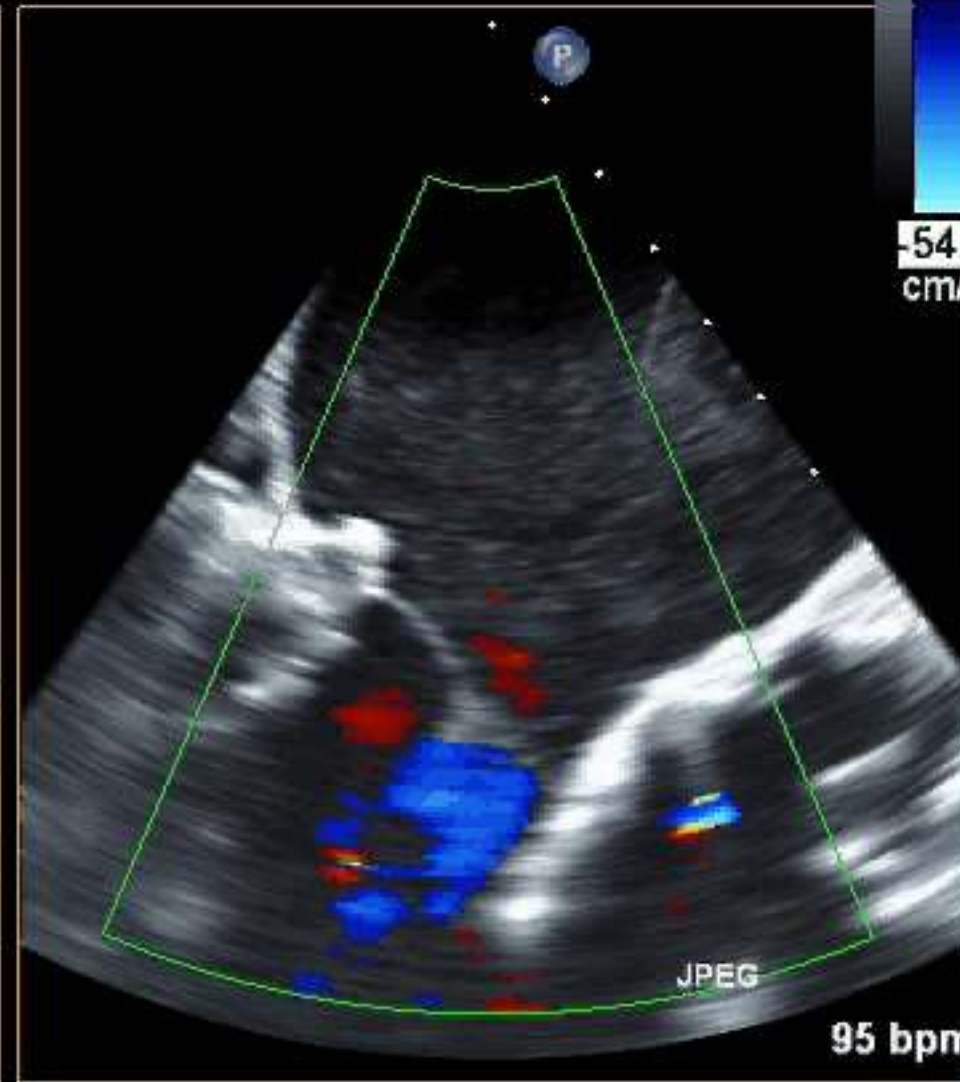
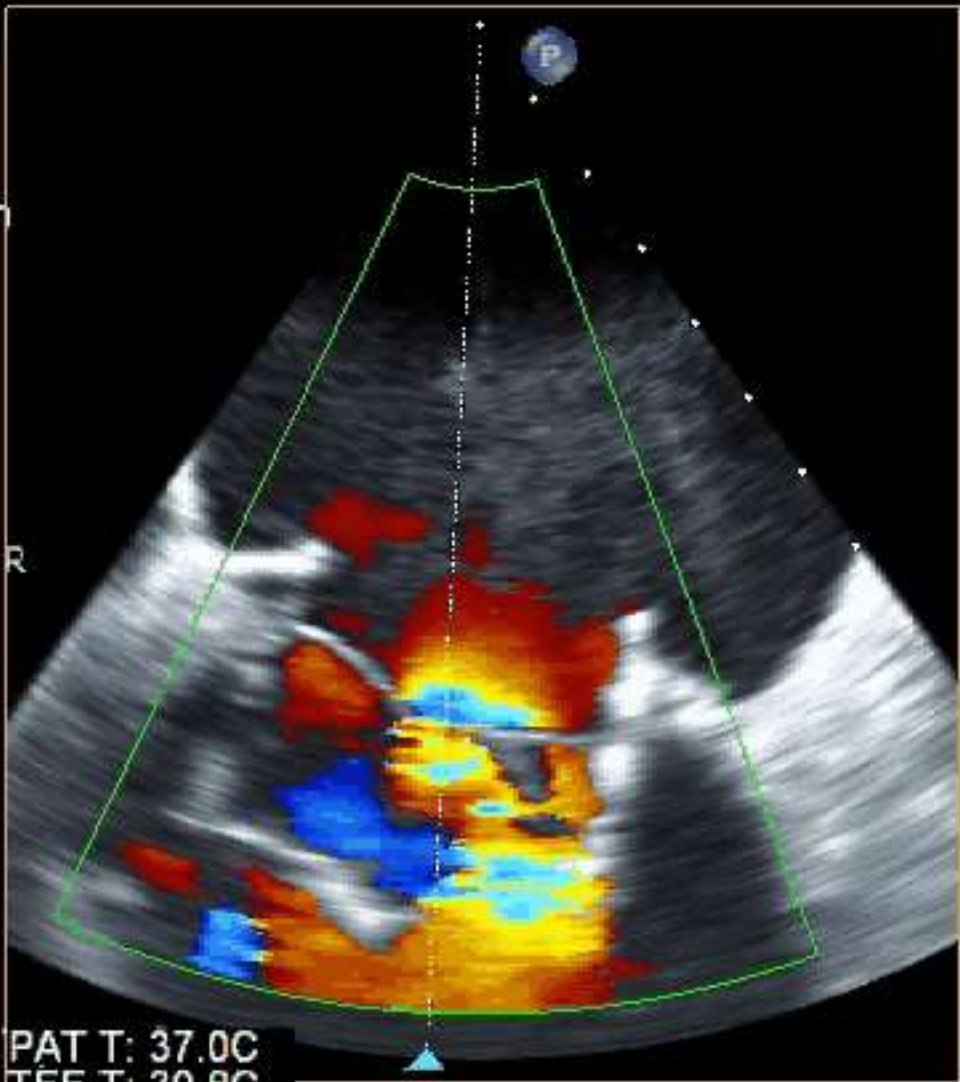


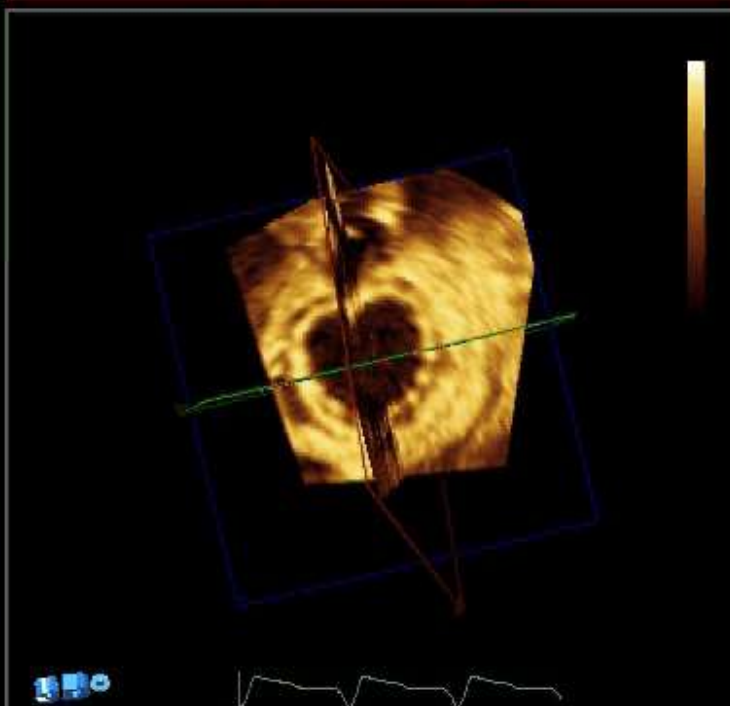
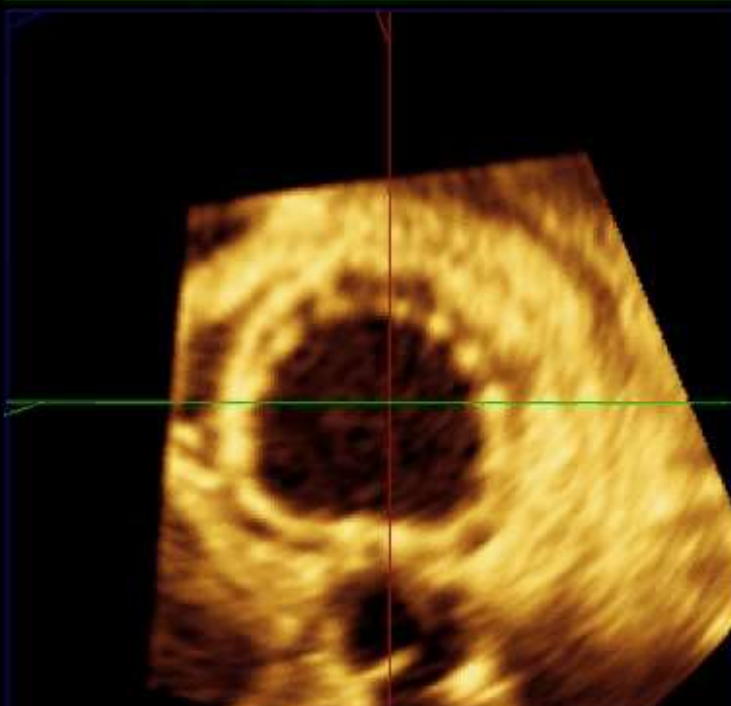
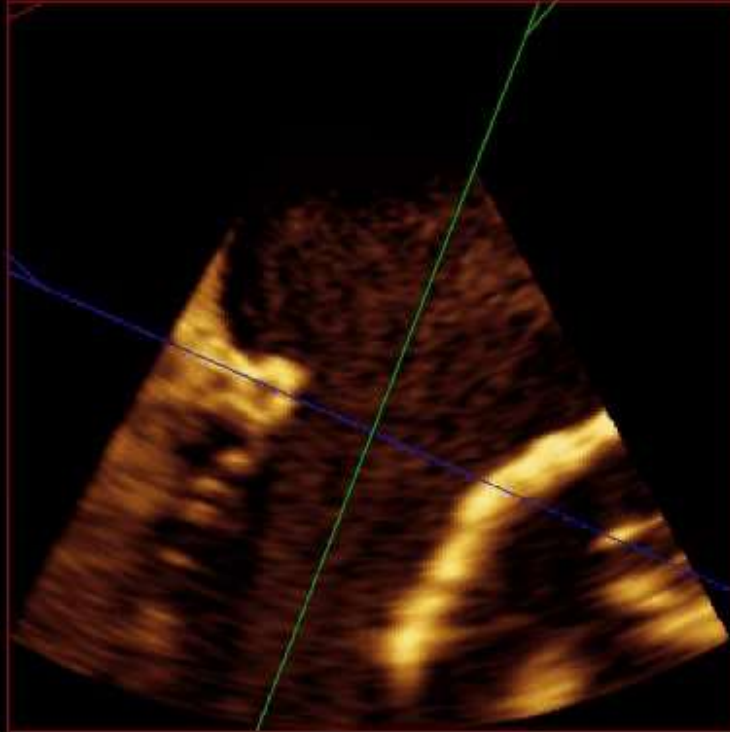
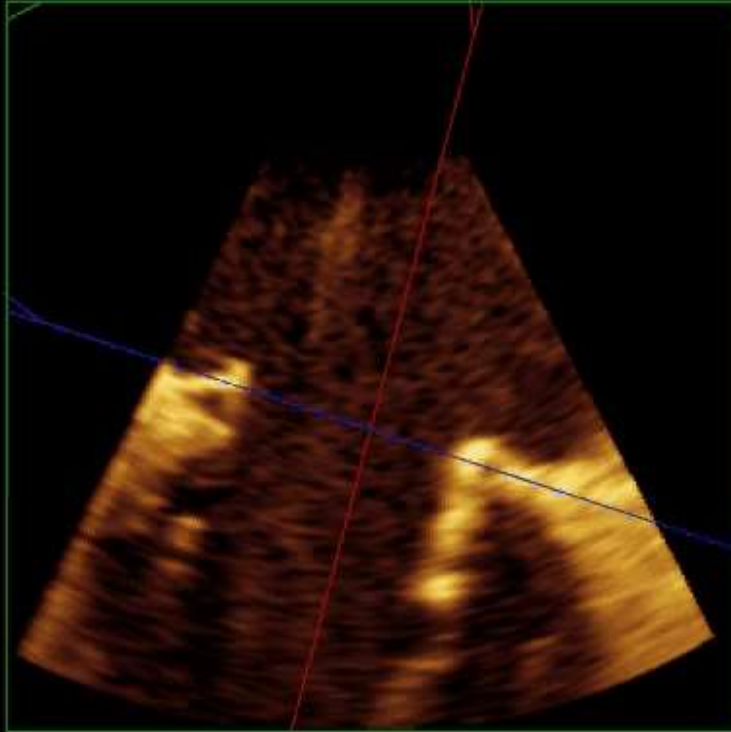
Incision 16 cm from midline





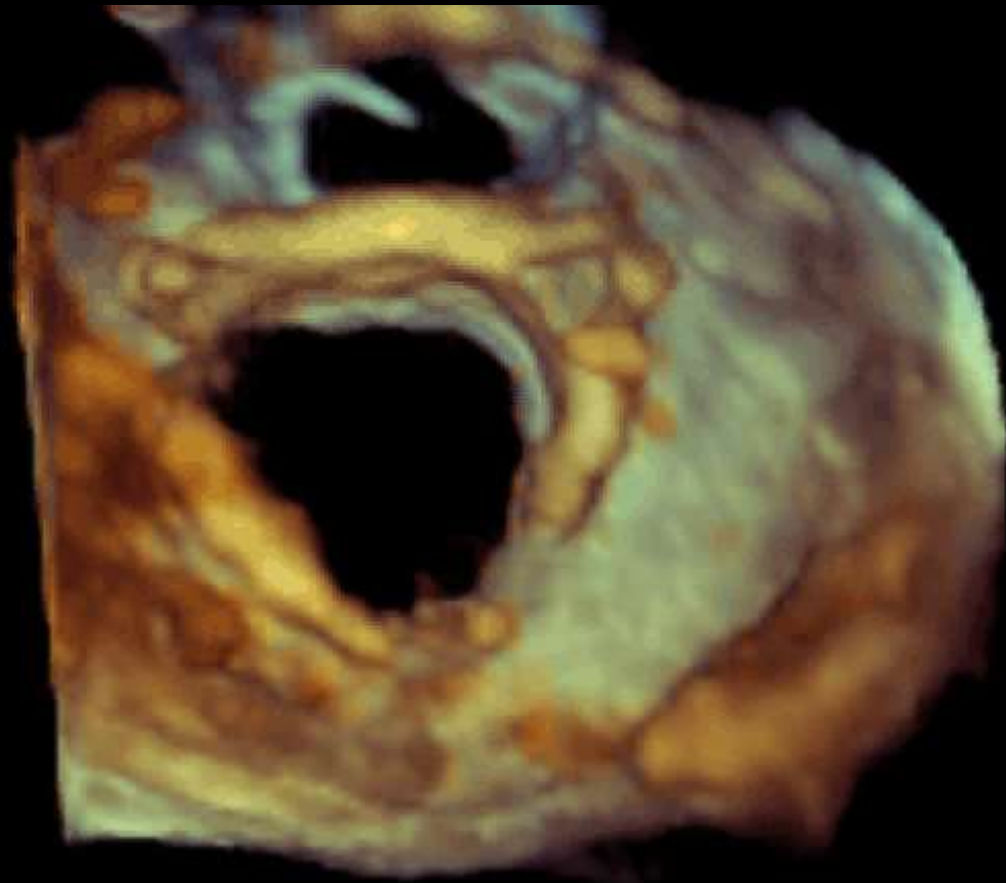
Well functional valve with no MR or PVL

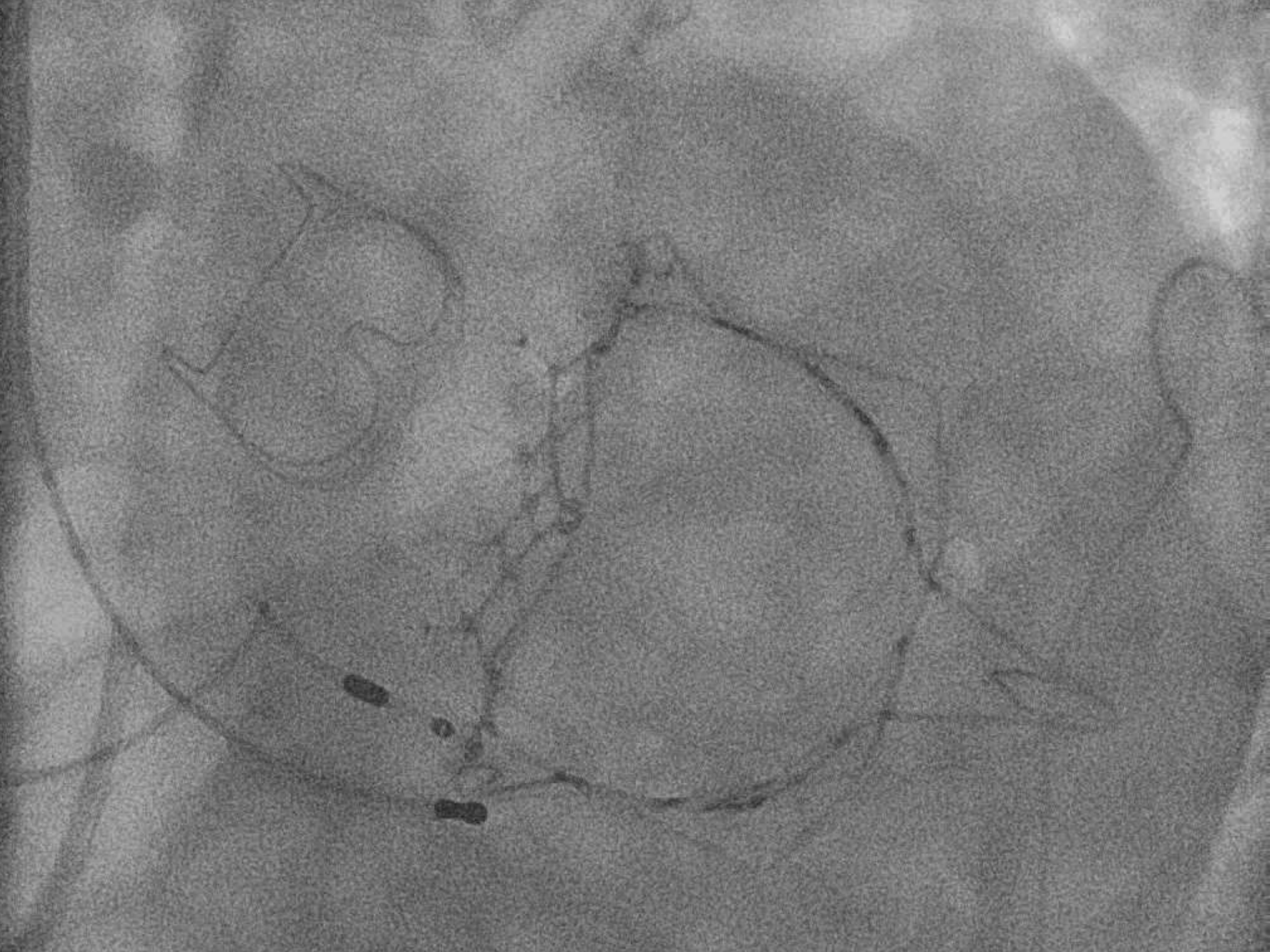




No LVOT Obstruction

10Hz
cm
e 3D
11%
50dB





Tiara Compassionate use: Patient Characteristics

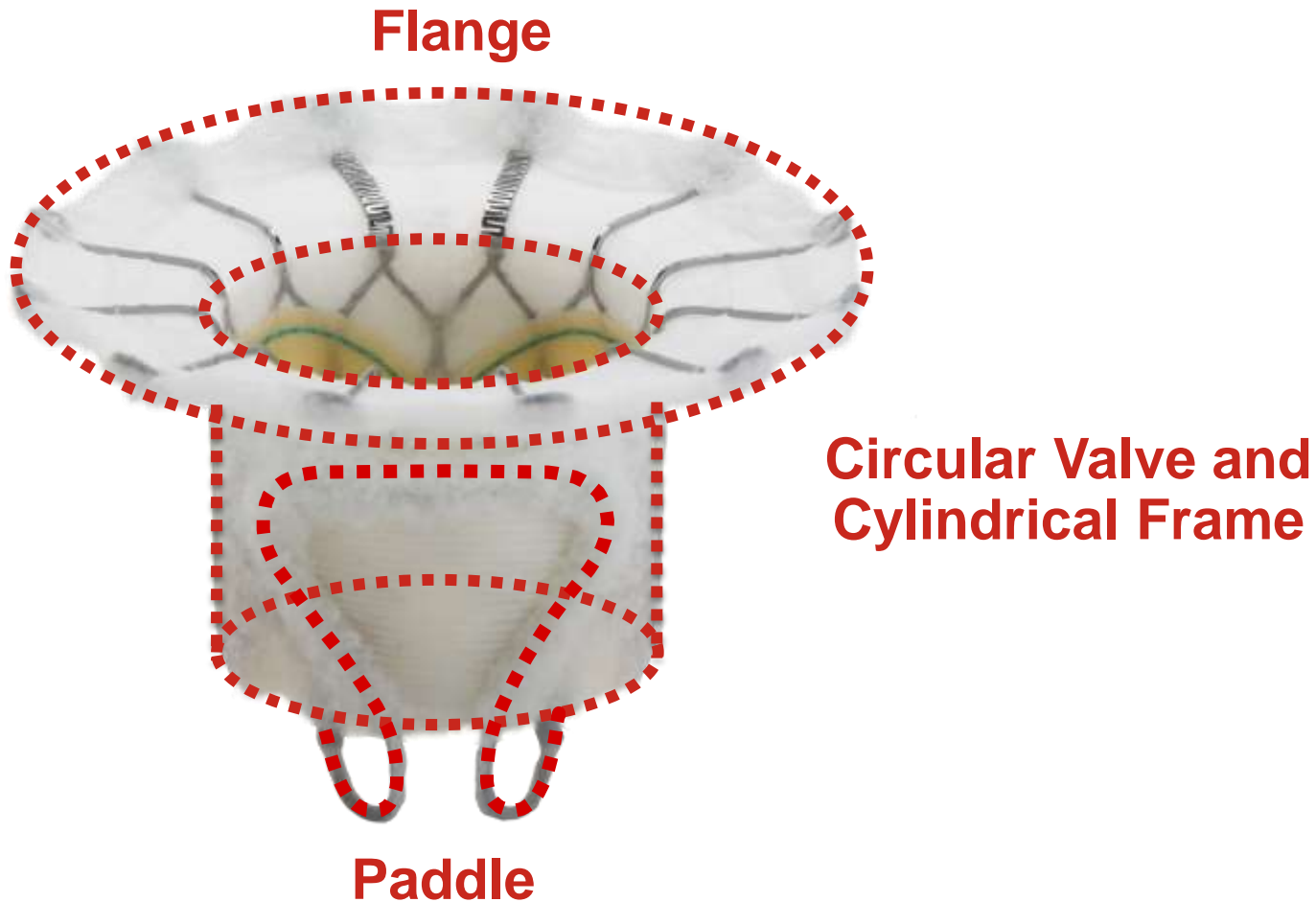
#	Age/ Gender	Etiology	NYHA	Comorbidities	STS (%)	LVE F (%)
1	73/M	Isch	IV	CRF (HD), pulm fibrosis (DLCO-22%), CRT-D	47.7	15
2	61/F	Isch	IV	Liver cirrhosis, CRF	5	25
3	39/M	Dilated	III	CRF, MitraClip aborted	2.4	20
4	79/M	Isch	III	CRF, CABG (1978, 1992), AVR (2012)	14.2	35
5	68/M	Isch/Valvular	IV	CRF, Mech AVR (1983), AVR (2013), CRTD, VT, CHF on inotropes	18.5	30
6	82/M	Rheumatic	III	CRF, Bentall with biological AVR, Recent PCI to LM, MS – MVG: 8 mmHg	13.8	45
7	81/M	Degenerative	III	S/P MV repair with a 29mm flexible ring (Barlow's), CRF, Chronic anemia	7.2	30
8	85/F	Isch	III	CRF, S/P PCI, Bleeding disorder	7.7	30
9	74/F	Isch	IV	CRF, Obesity, Ventricular and atrial tachyarrhythmia, DM, HTN, S/P CABG, anemia	11.7	45
10	89/F	Degenerative	III	CRF, COPD, S/P CABG,	16.1	65
11	64/M	Isch	III	CRF, S/P CVA, rupture pap muscle	5	30

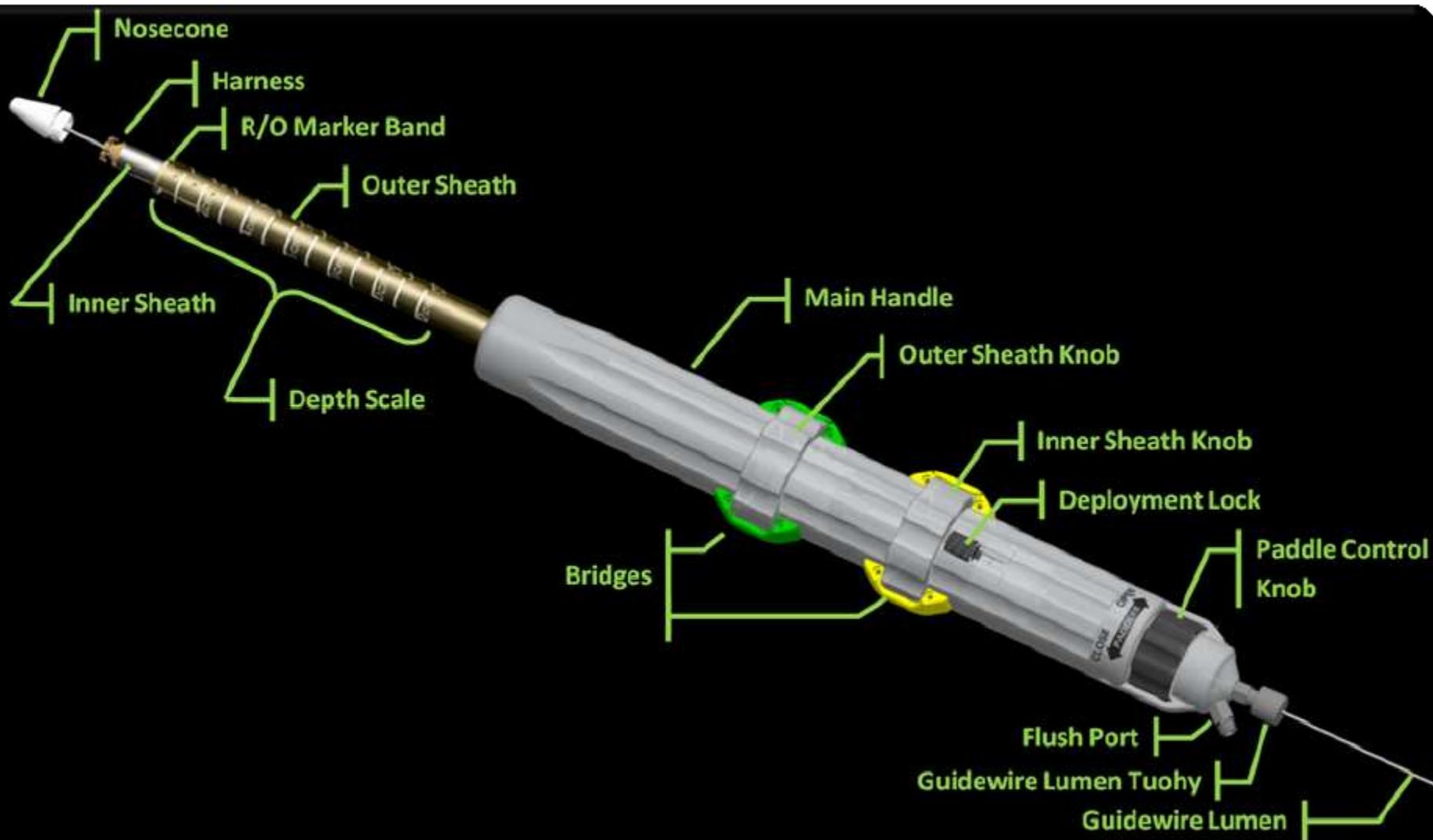
TIARA compassionate use experience

Of the 9 patients with successful implantation:

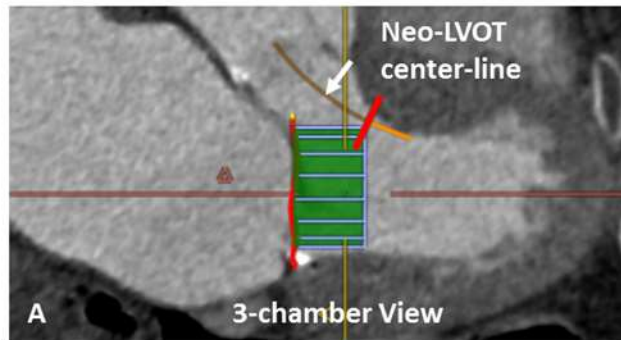
- Average Implantation Time: 21 min
(from apical puncture to apical closure)
- No CPB
- No MR, no PVL
- No significant tran-svalvular gradient
- No LVOT gradient
- No LCx artery or coronary sinus obstruction
- Longest follow up 2 years, both patients with excellent valve function

Edwards FORTIS Transcatheter Mitral Valve

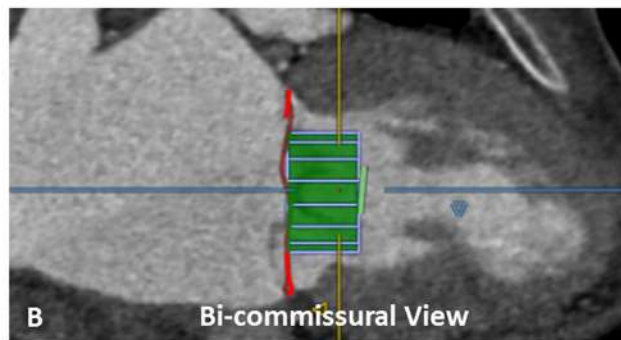




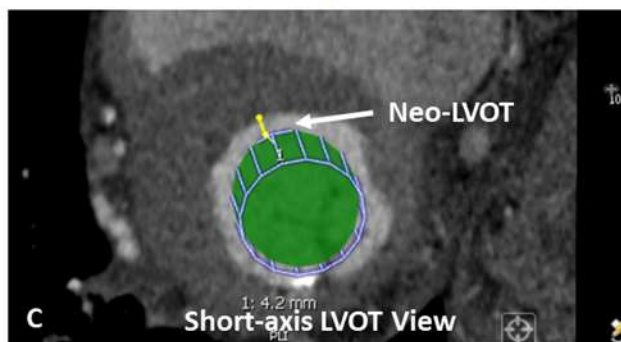
Prediction of new-LVOT dimensions



A. Three-chamber view. Depicting the simulated cylindrical virtual valve implant



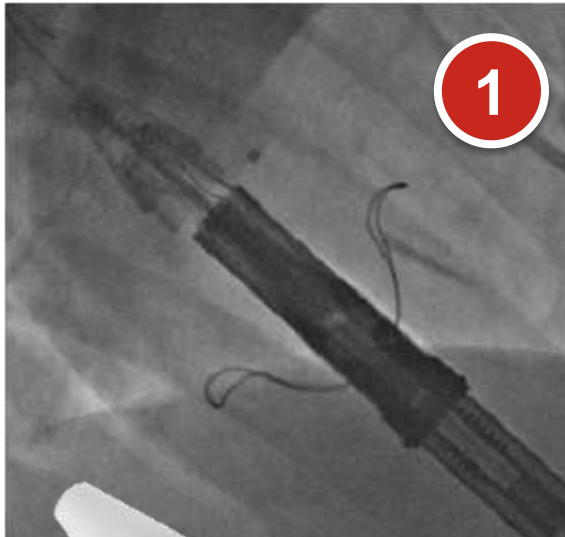
B. Bicommisural view. The red bar indicates the orientation and position of the short-axis LVOT view



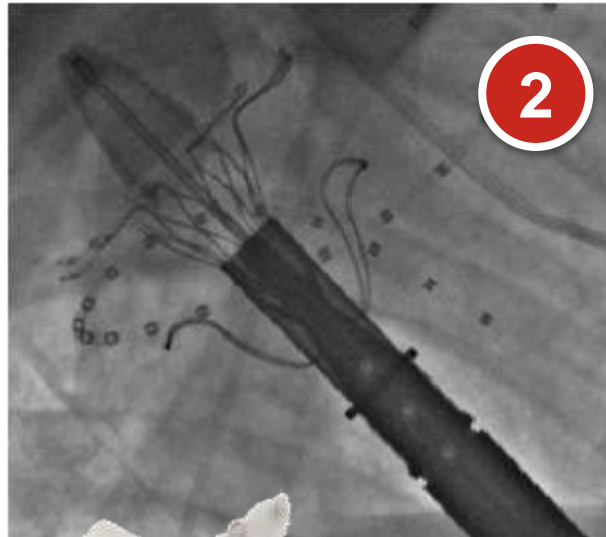
C. Short-axis view. The neo-LVOT is slit-like, suggestive of high risk for LVOT obstruction.

Edwards FORTIS TMVR Procedure

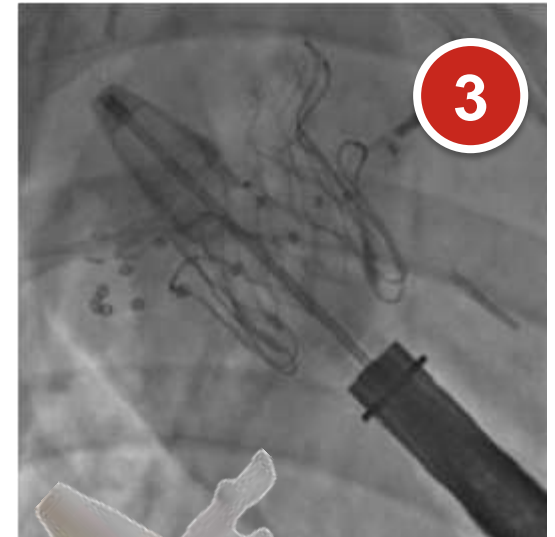
Leaflet Capture



Flange Release



Valve Release



Paddles capture AML and PML

PHILIPS
MUNT
FR 50Hz
10cm
2D
74%
C 48
P Off
Res
0 0 180
FORTIS SPH 1
PAT T: 37.0C
TEE T: 38.1C
91

07/15/2014 12:22:23PM TIS0.1
ST. PAULS OR X7-2t/SP 3DTEE

CASEY, JACLYN
DOB: 01/15/1988
P: 01/15/2014

CASEY, JULY 15 '14
IST: 5KV CARD
104.1mA 85.5Ohm
Pr Case: 07_2-14
REFL: 2040
I: 00:18:04
32%

Cursor

Atrial flange opened and valve released

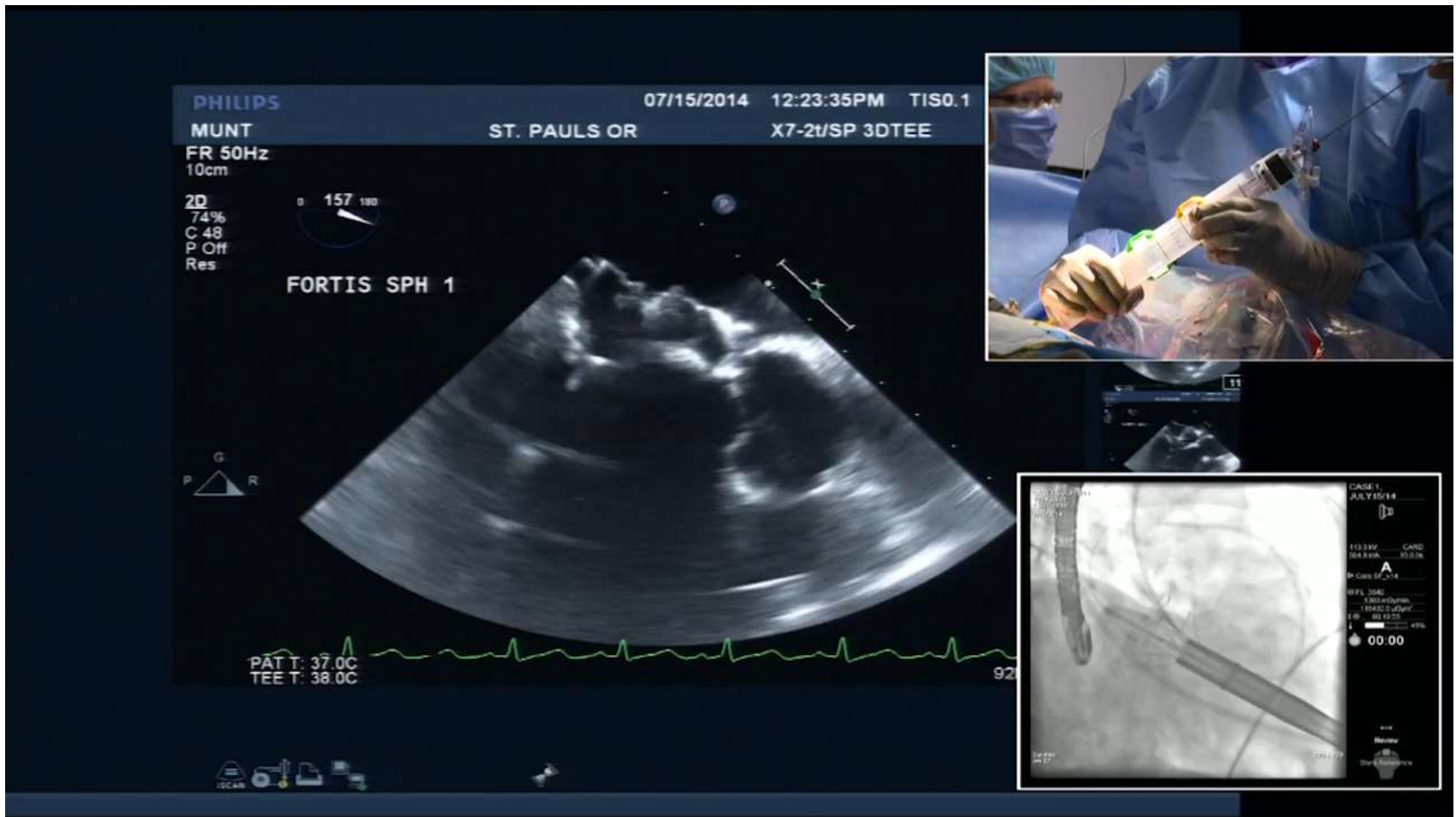
Atrial flange opened



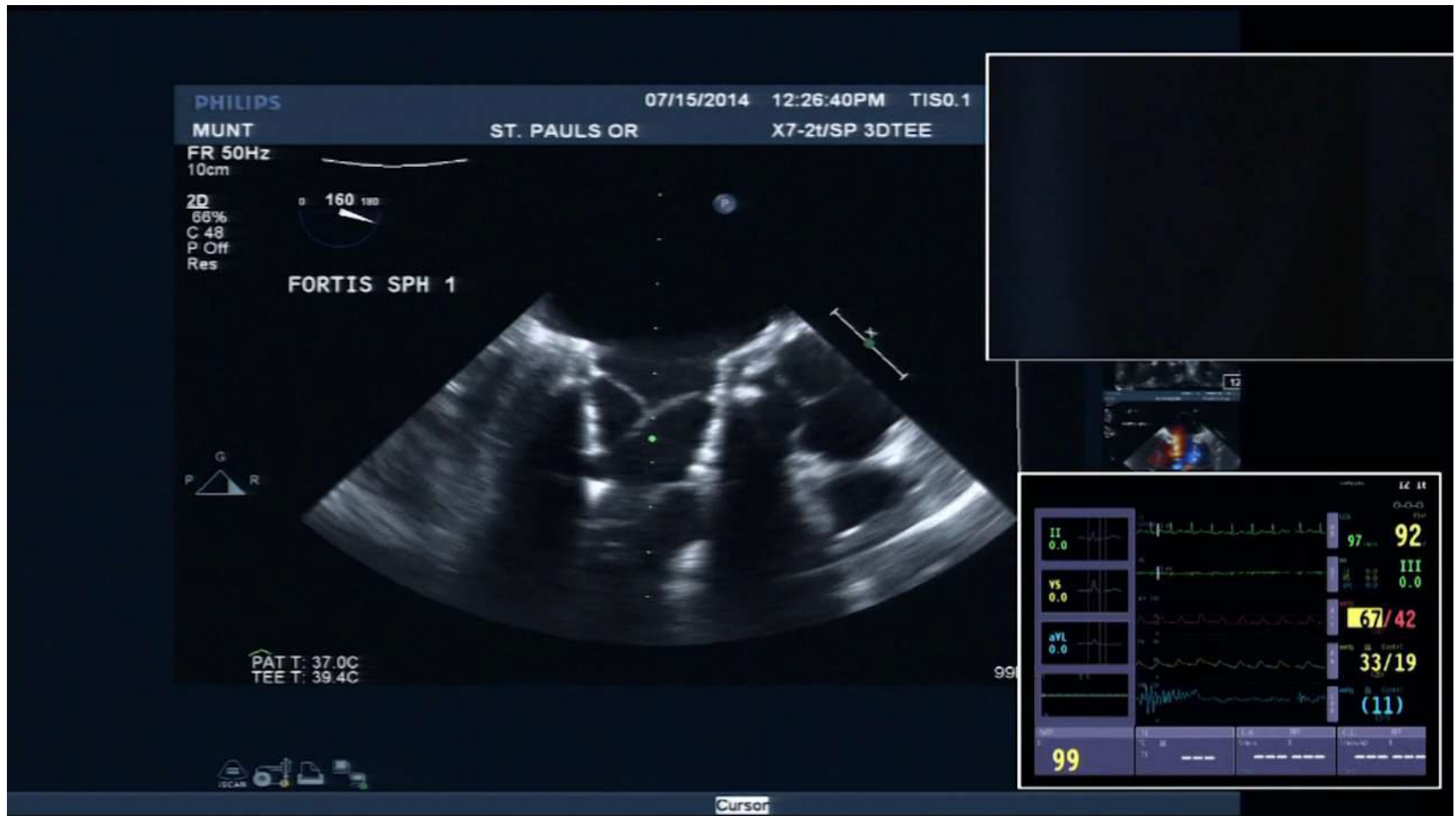
Valve released



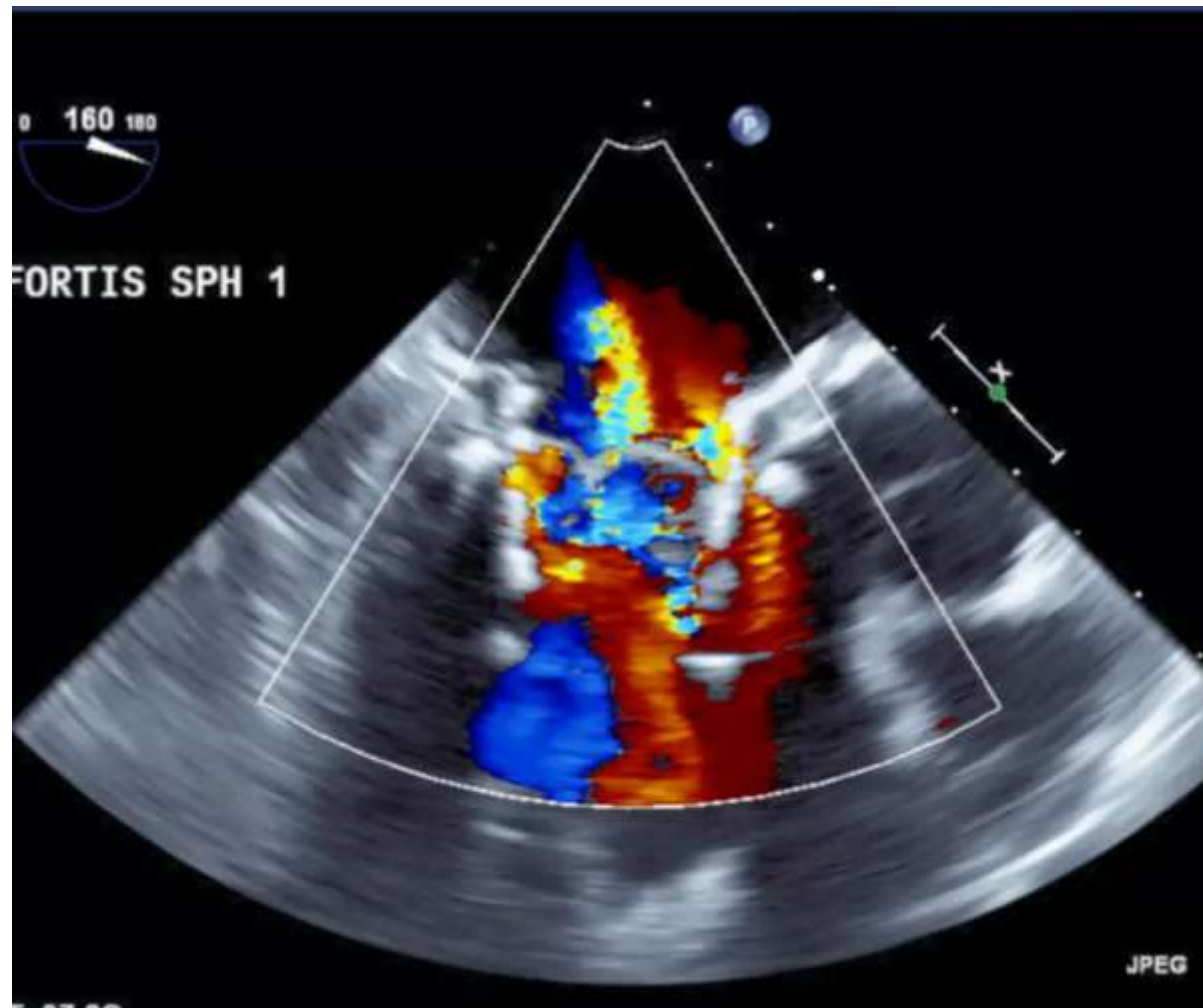
Valve released, nosecone withdrawn



Delivery system removed

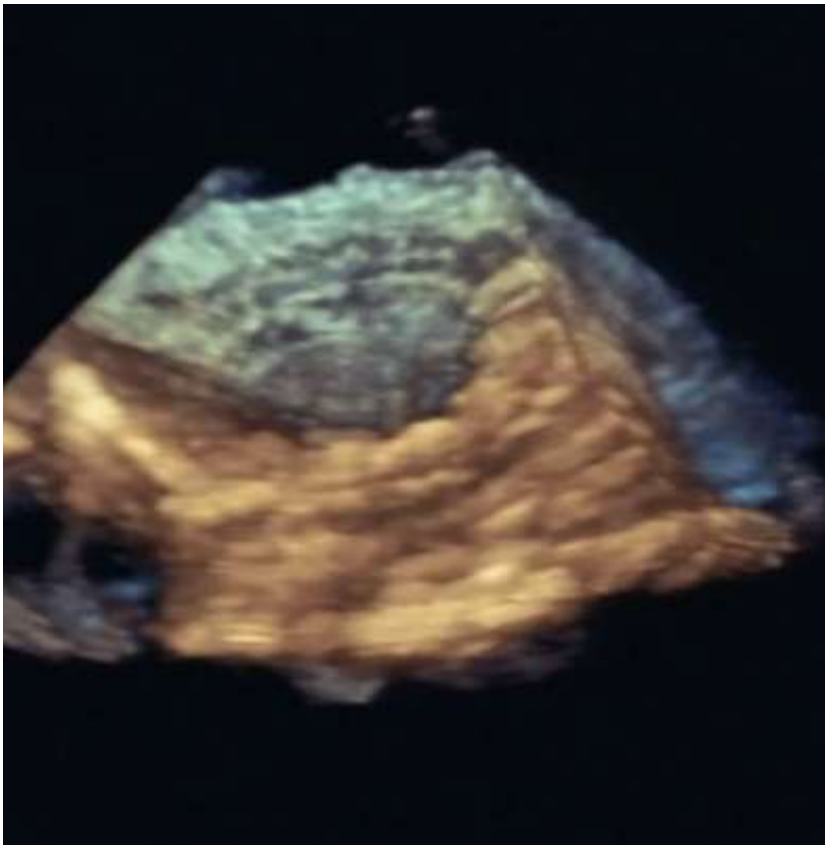


TEE post-Fortis implant

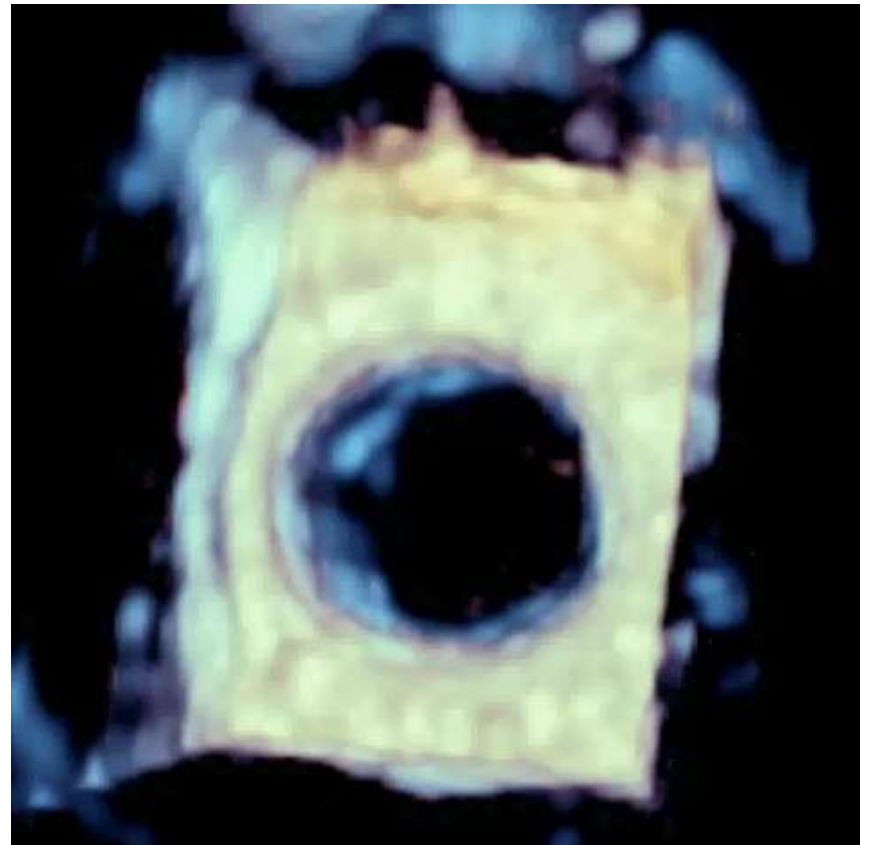


3D TEE

From LA

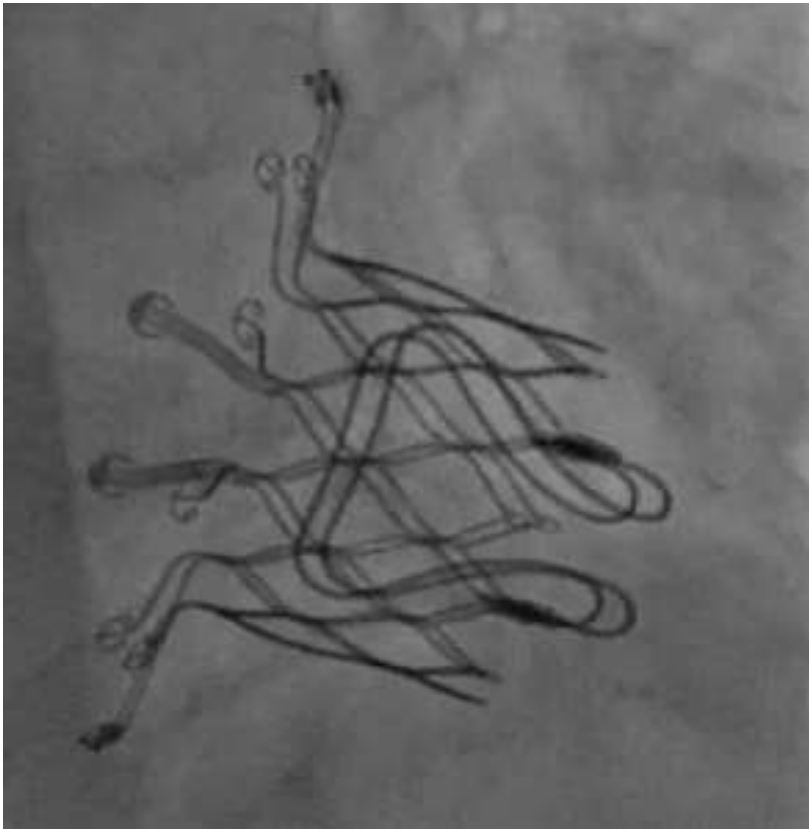


From LV

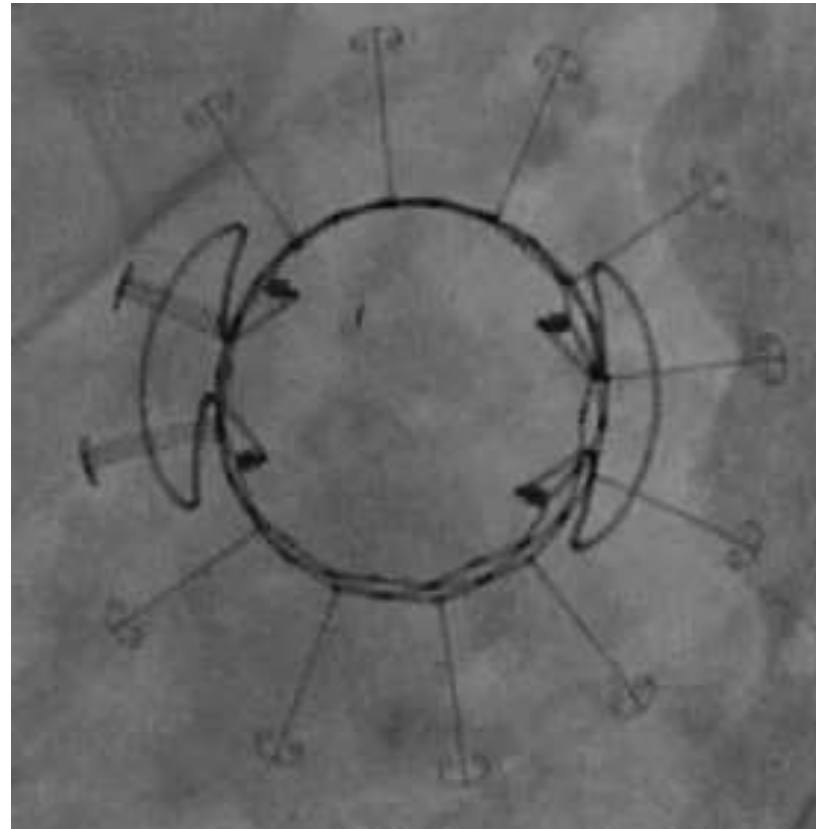


Fluoroscopy

RAO



LAO Cau

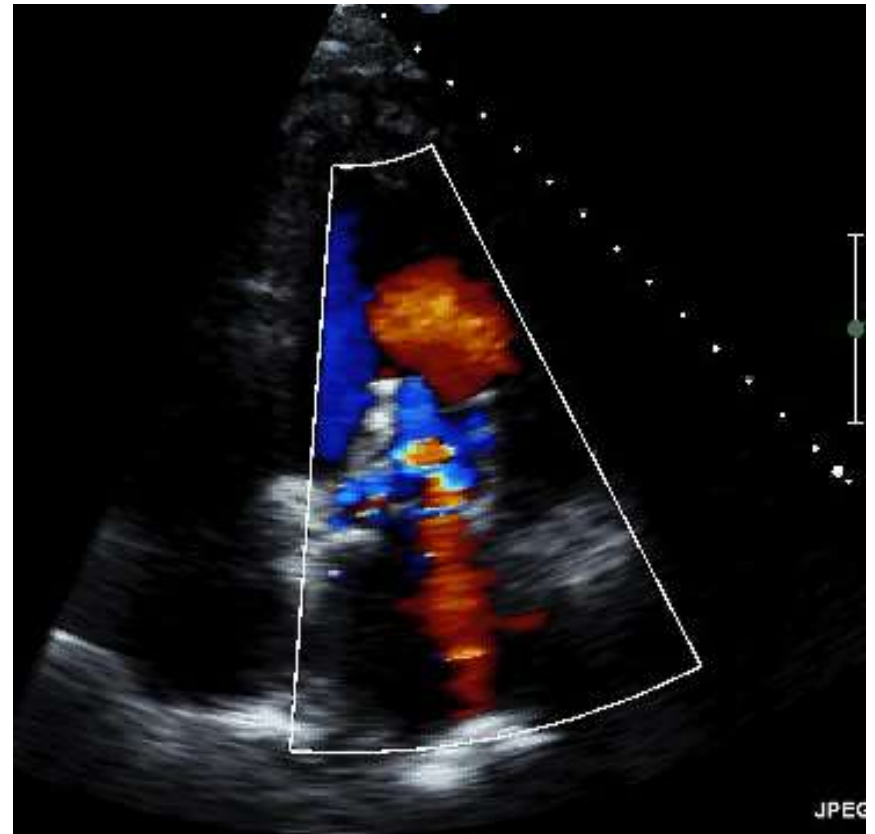


TTE 6 months, remains well at 2 years

Valve stable, LVEF 45%



MR trivial, MG 3mmHg



Tendyne TMVR (Abbott)



- Self-Expanding Nitinol Outer Frame
- D-Shaped
- Porcine Pericardial Tri-Leaflet Valve
- Numerous sizes available
- Valve Tethered to Apex
- Apical Pad Assists in Access Closure

Tendyne TMVR

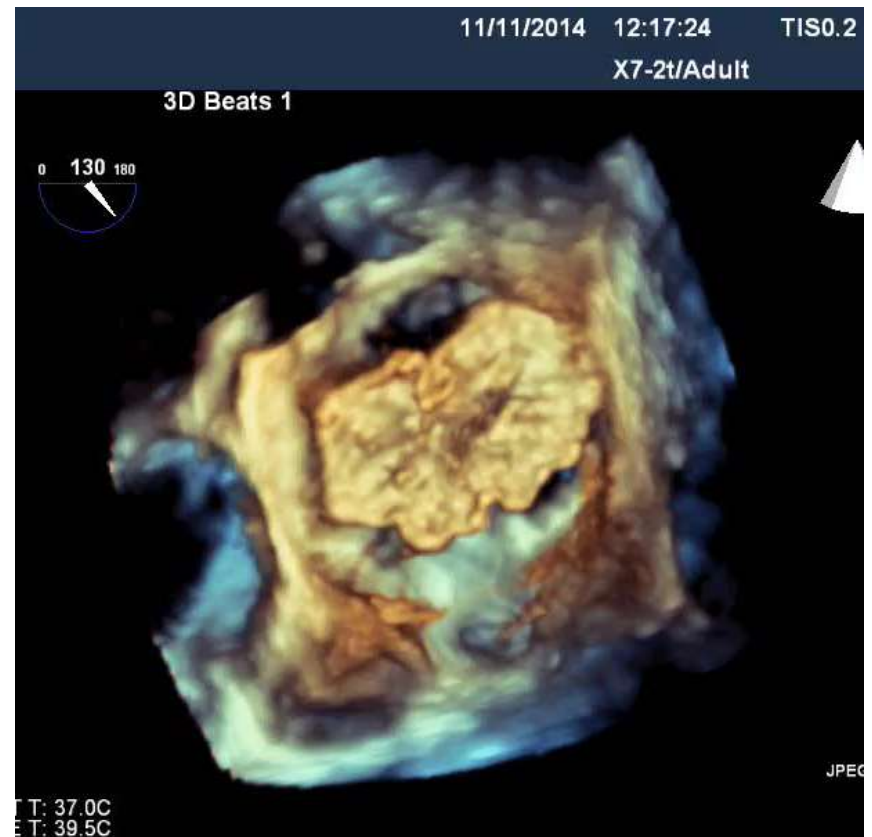


Tendyne deployment

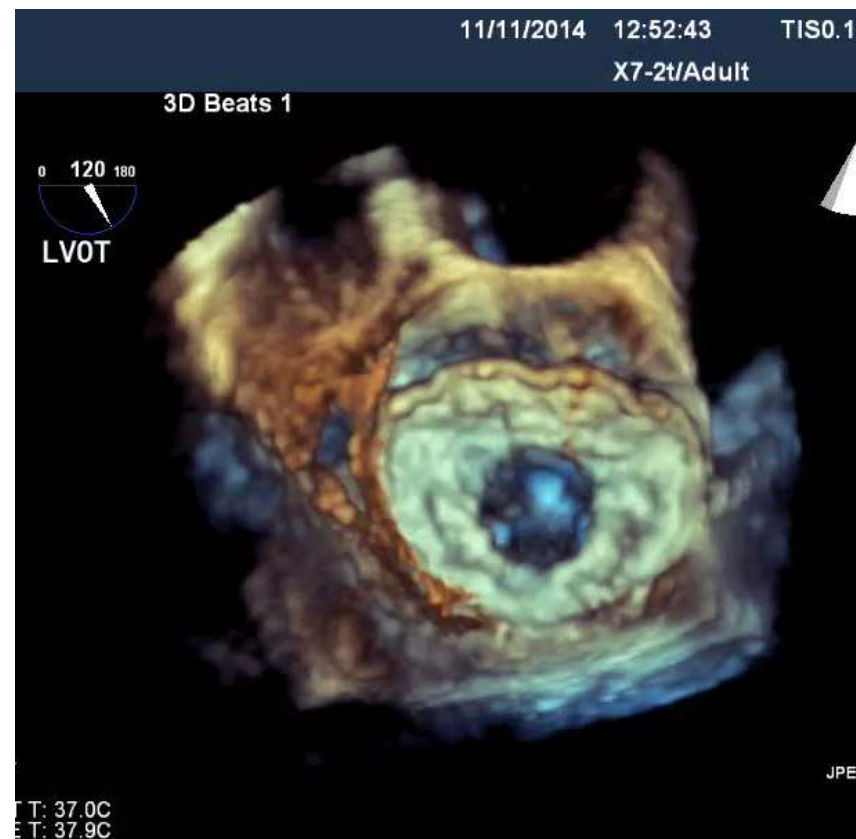
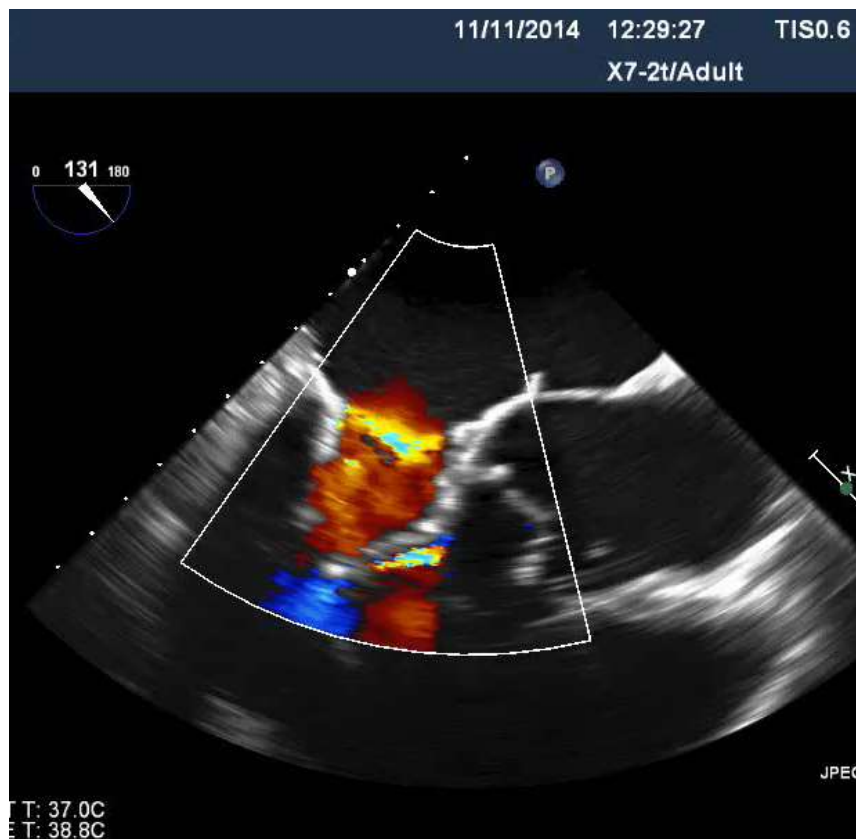
Device centred



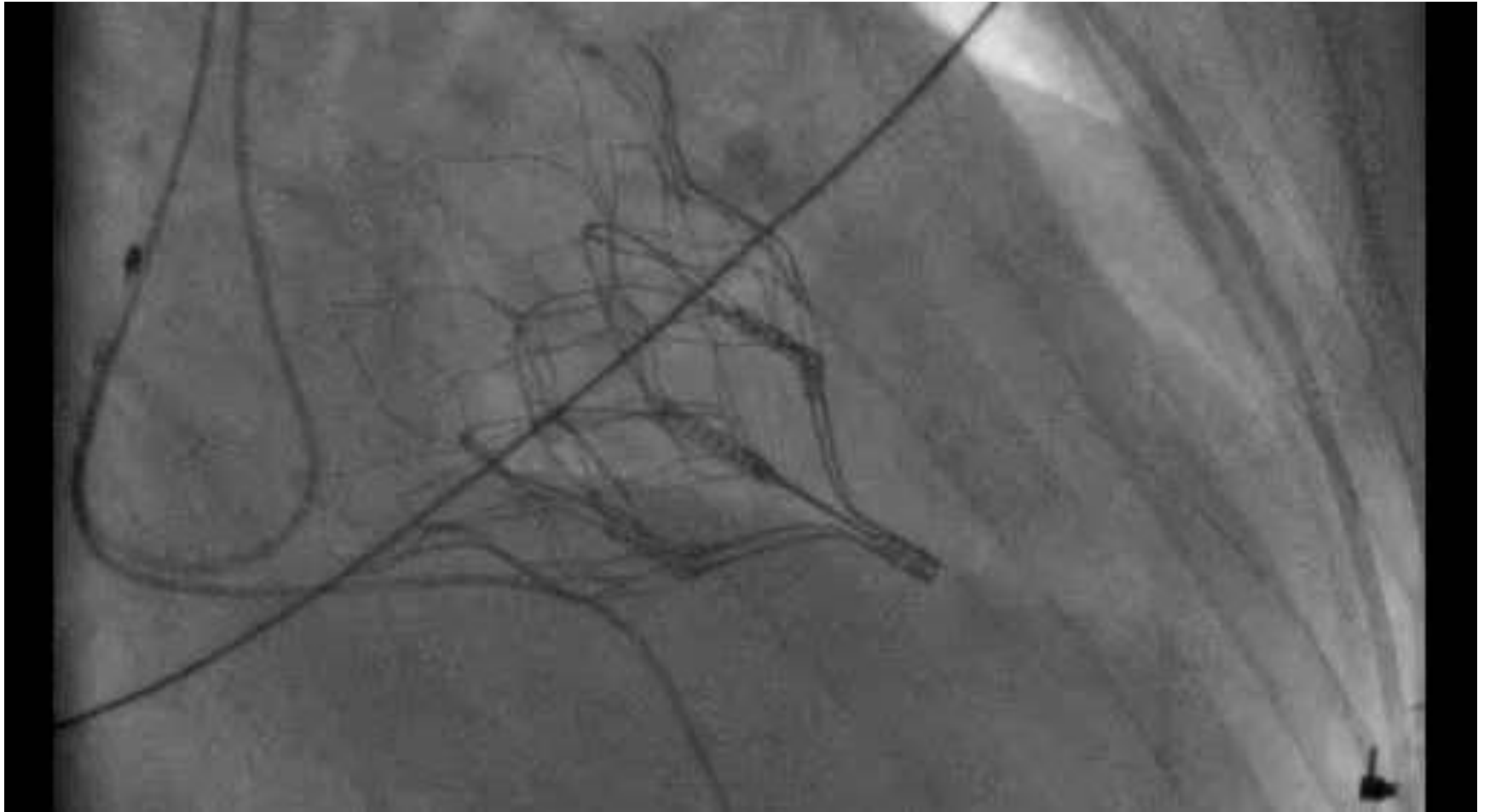
Atrial skirt



Tendyne



Tendyne



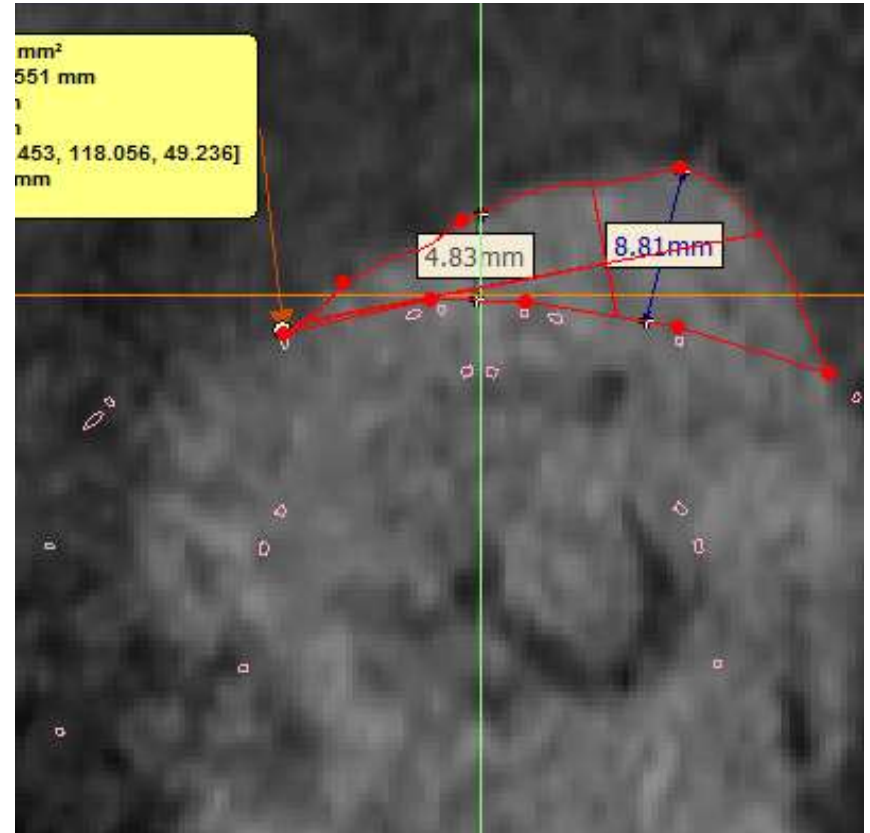
Case: Patient at risk of LVOT obstruction

TEE



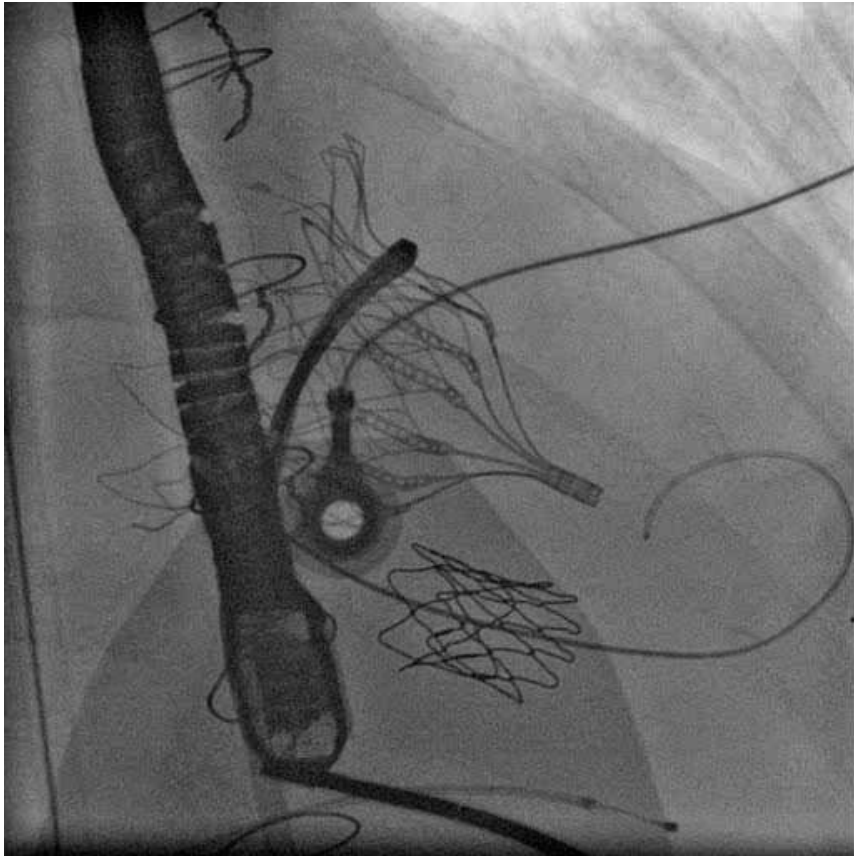
Aortic-mitral angle is acute

CT



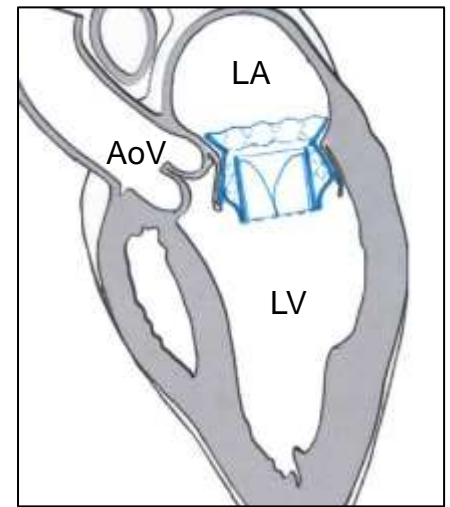
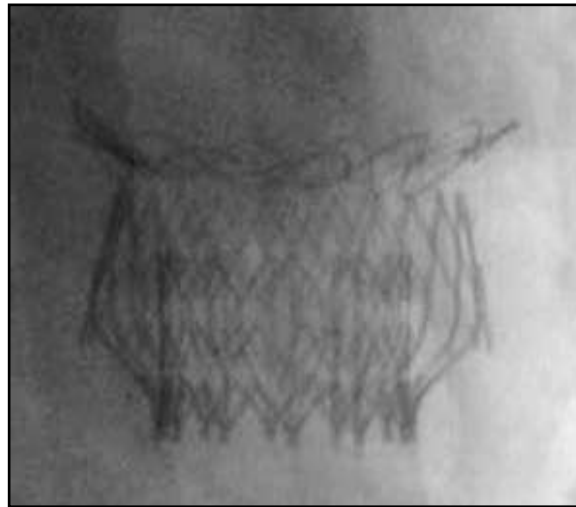
Neo LVOT is small

LVOT stenting



Twelve/Intrepid TMVI (Medtronic)

- Fixation & sealing are achieved by
 - Variable stiffness along the height of the Outer Stent produces a cork effect
 - Radial force, small cleats, frictional elements & tissue ingrowth
 - Leveraging, but not relying on, the native leaflets



Intrepid (Medtronic)

Atrial view



27mm bovine tricuspid valve

Left ventricular view

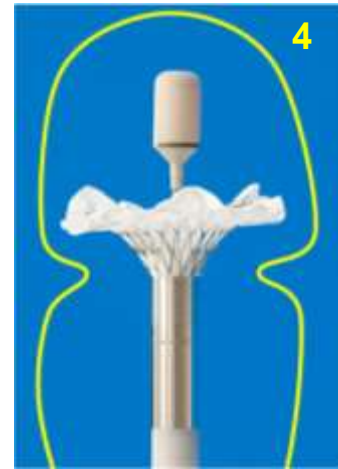
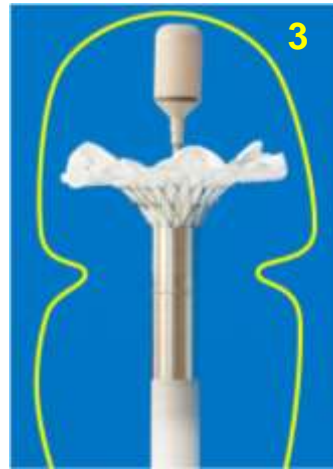
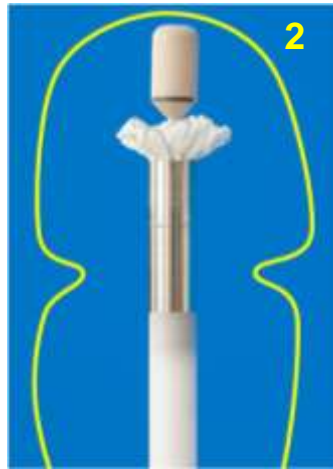
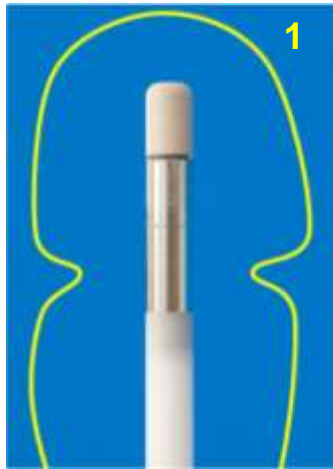


Inner stent

Outer stent

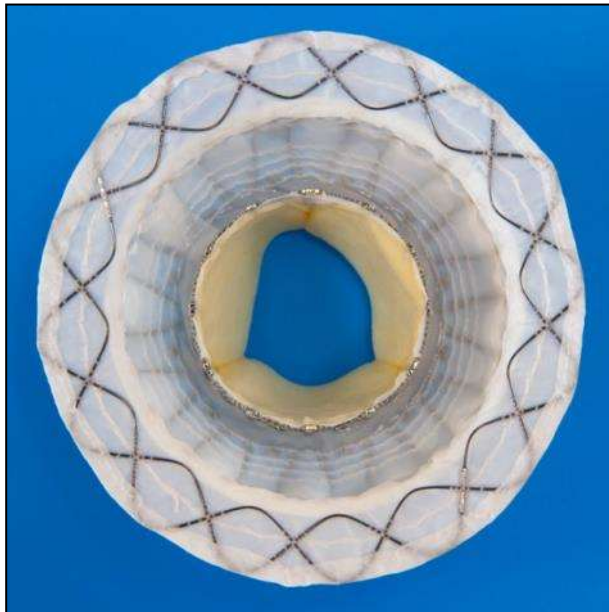
Straightforward Apical Procedure

Controlled deployment of self-expanding implant

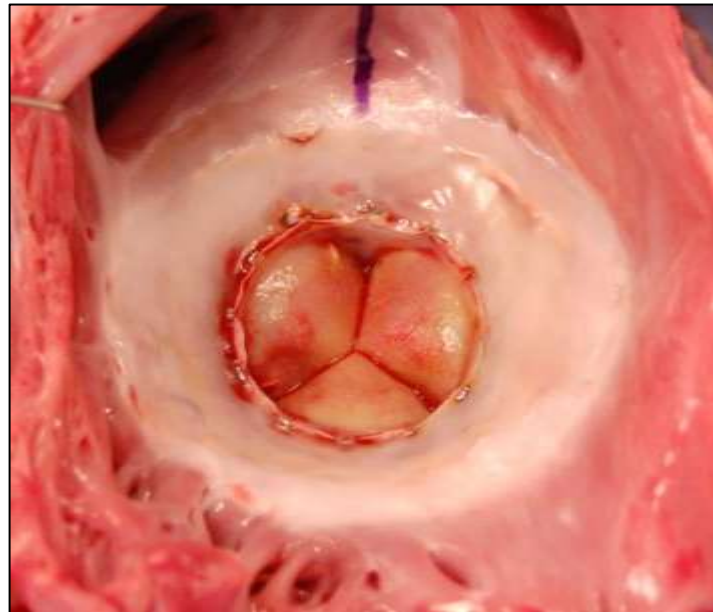


Intrepid (Medtronic)

- Fixation & sealing are achieved by
 - Variable stiffness along the height of the Outer Stent produces a cork effect
 - Radial force, small cleats, frictional elements & tissue ingrowth
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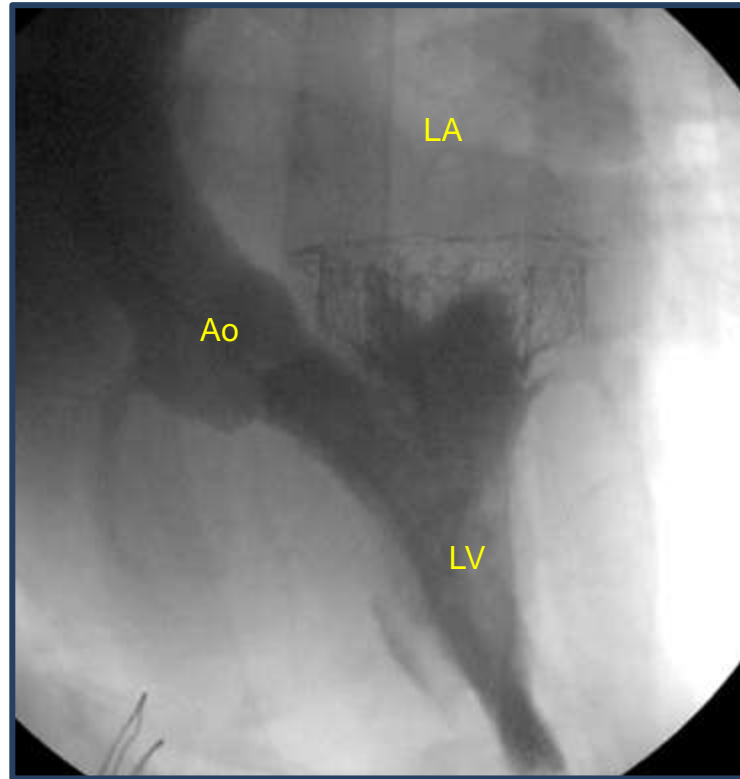


Implant with atrial brim



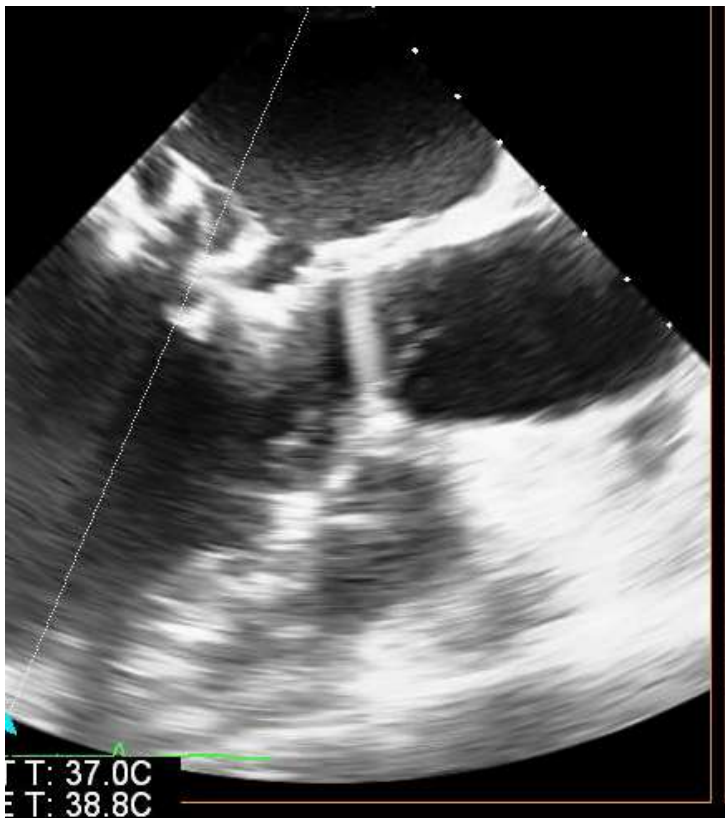
Atrial view (94 days in vivo)

Animal study: Patent LVOT

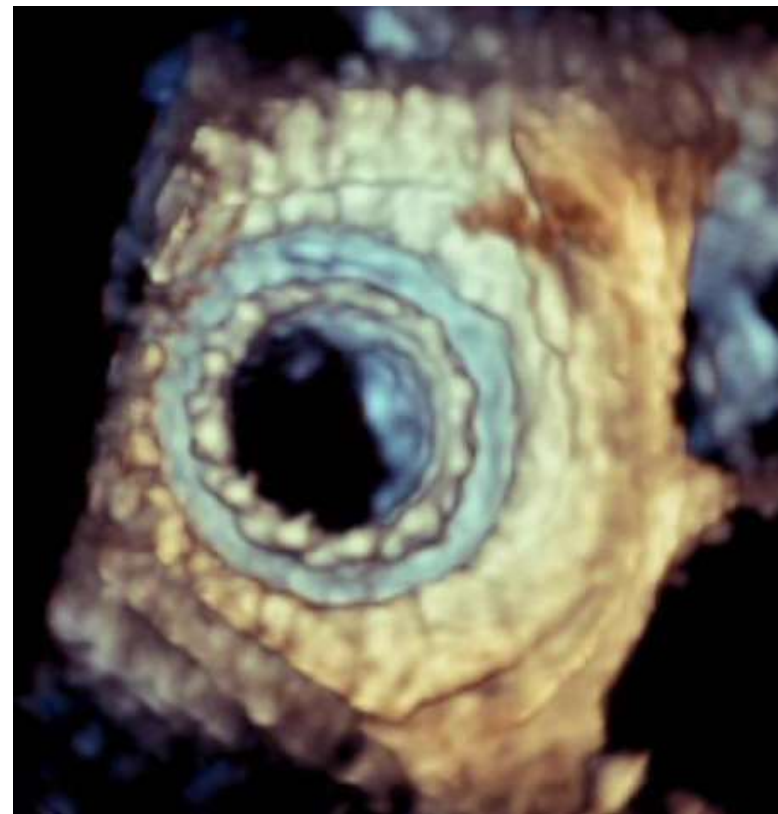


Intrepid: human implant

TEE 2D LAX



TEE 3D from LA



Thankyou