

August 17-19, 2016

Sheraton Grande Walkerhill Hotel, Seoul, Korea

# Transcatheter Valve-in-Valve for Dysfunctional Mitral Bioprosthesis: Sapien XT vs. Lotus Valve

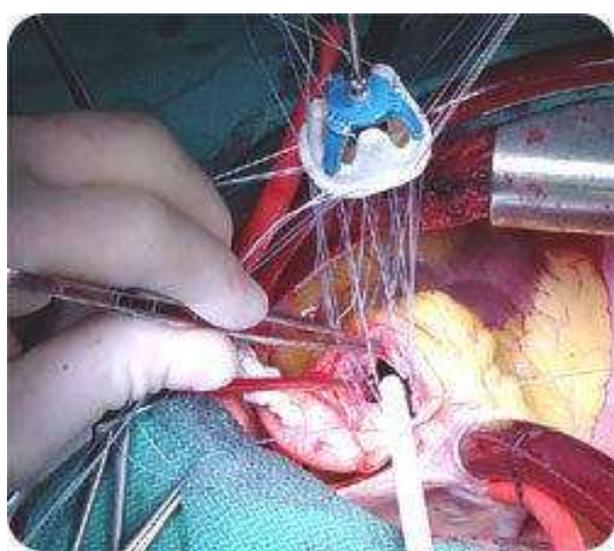


**Wei-Hsian Yin, MD, PhD, FESC, FAPSC.**

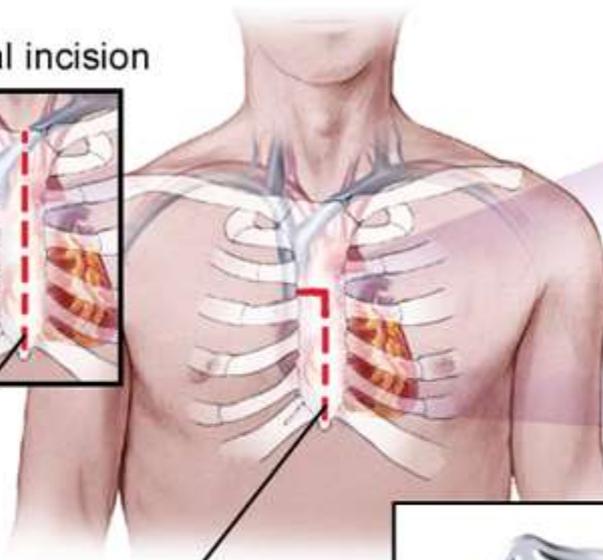
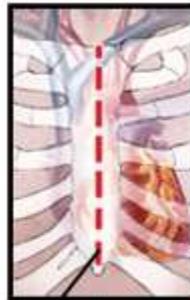
**Chief, Division of Cardiology, Heart Center,  
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# Valve-in-valve Implantation for failed Bioprostheses: a new frontier of TAVI

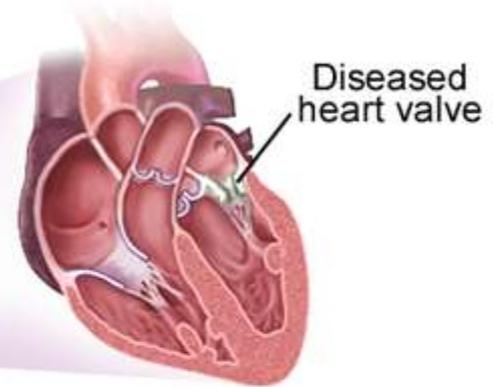
- The clinical use of bioprosthetic valves in the treatment of valvular heart disease has been growing during the past 2 decades.



Typical incision

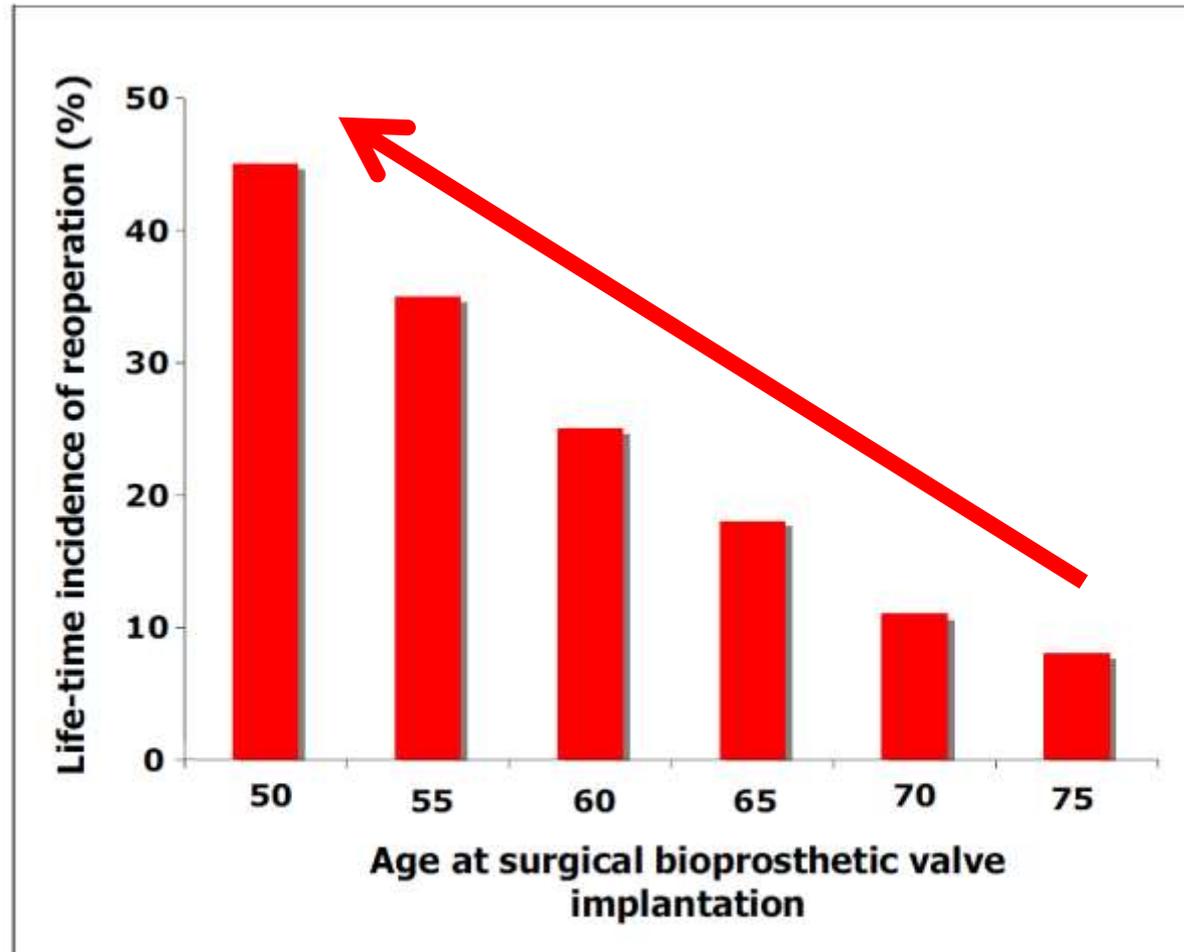


Incision for minimally invasive heart valve surgery



- At the same time, there is an expanding population of complex and high-risk elderly patients who require redo operations because of bioprosthetic valve dysfunction.

**The lifetime risk of reoperation decreases with increasing patient age at the time of implantation.**



➤ **With time, bioprosthetic tissue can be expected to deteriorate and eventually fail.**

# Valve-in-valve Implantation for failed Bioprostheses: a new frontier of TAVI

A



Wear and tear

B



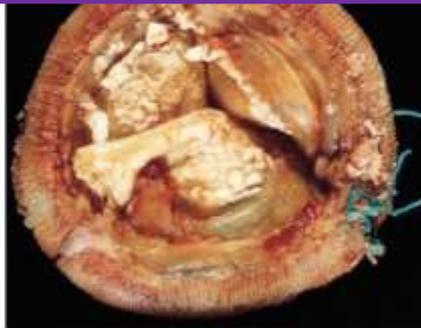
Calcification

C



Pannus

The operative mortality for an elective redo aortic valve surgery is reported to range from **2% to 7%**, but this percentage can increase to **more than 30%** in **high-risk and non-elective patients**.



Endocarditis

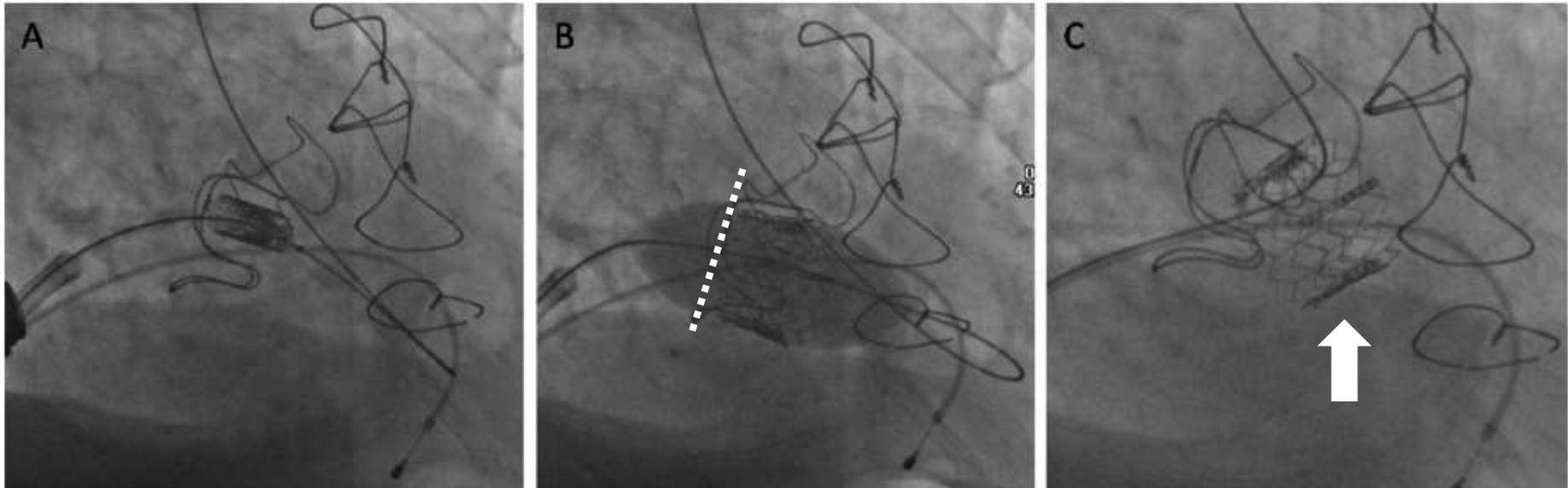


Thrombus

# Transcatheter Valve-in-Valve Implantation for Failed Bioprosthetic Heart Valves

John G. Webb, MD; David A. Wood, MD; Jian Ye, MD; Ronen Gurvitch, MD; Jean-Bernard Masson, MD; Josep Rodés-Cabau, MD; Mark Osten, MD; Eric Horlick, MD; O. Wendler, MD; Eric Dumont, MD; Ronald G. Carere, MD; Namal Wijesinghe, MD;

- **A first-in-human attempt using a percutaneous transeptal approach for transcatheter mitral VIV was unsuccessful.**



- **Noncoaxial and too ventricular positioning of the THV within the surgically implanted prosthesis resulted in embolization.**

*(Circulation. 2010;121:1848-1857.)*

# Transcatheter Valve-in-Valve Implantation for Failed Bioprosthetic Heart Valves

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**Table 3. Mitral Valve-in-Valve Implantation: Valve Characteristics at Baseline and After the Procedure**

- **In the second patient, an open transatrial approach was attempted.**
- **Stable cannulation and coaxial positioning within the mitral prosthesis could not be accomplished, and the procedure was converted to a transapical approach.**

2	Baxter Edwards (model 6900P)	25	S	Atrial & apical	26	17	6	328	117	1	N/A
3	Edwards SAV (model 6650)	27	R	Apical	26	8	9	N/A	N/A	4	0
4	Edwards SAV (model 6650)	27	R	Apical	26	10	9	93	105	4	0
5	Medtronic Mosaic (model 310)	25	S	Apical	26	18	9	301	183	1	1
6	Edwards SAV (model 6650)	27	R	Apical	23	11	8	130	121	4	1*
7	Medtronic Intact (model 705)	27	R & S	Apical	23	20	7	198	164	4	1†

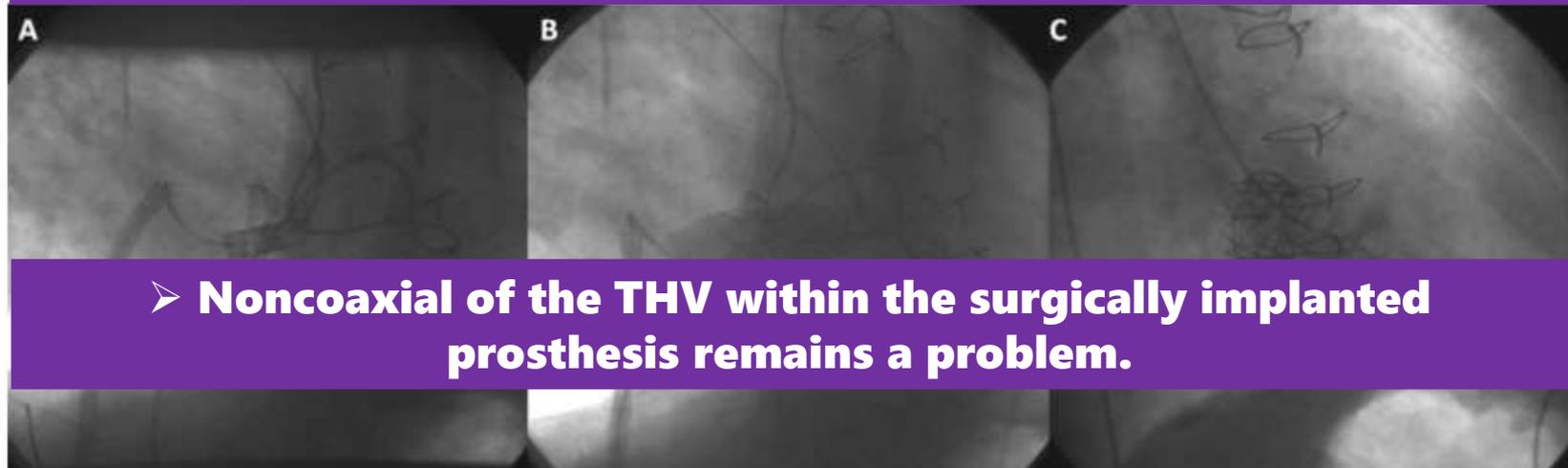
- **After that, all 5 subsequent implantations were successfully performed with transapical access.**

# Successful Percutaneous Anterograde Transcatheter Valve-in-Valve Implantation in the Mitral Position

Transvenous access

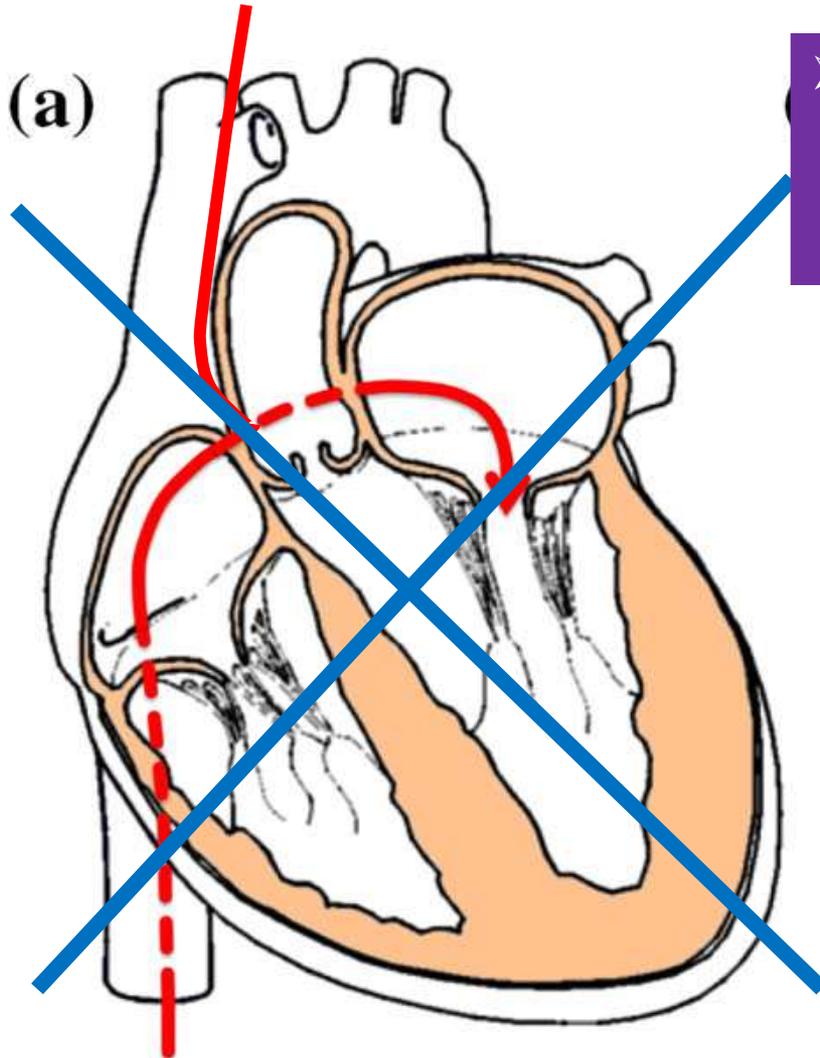


➤ The procedure is time-consuming and carries a higher risk.

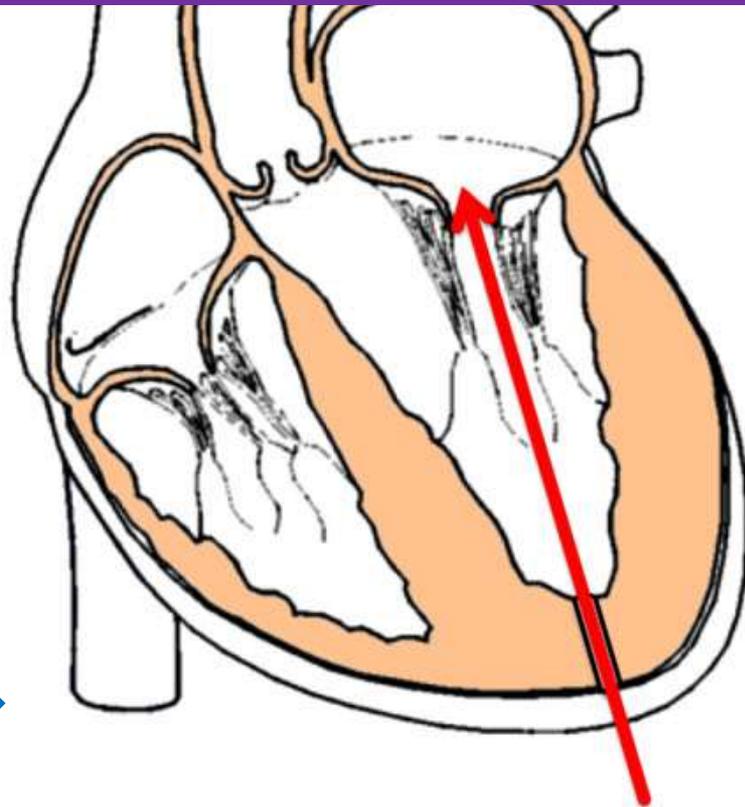


➤ Noncoaxial of the THV within the surgically implanted prosthesis remains a problem.

# Transvenous vs. transapical approach for mitral VIV



➤ A direct and coaxial access to the mitral prosthetic valve can be achieved from the left ventricular apex.





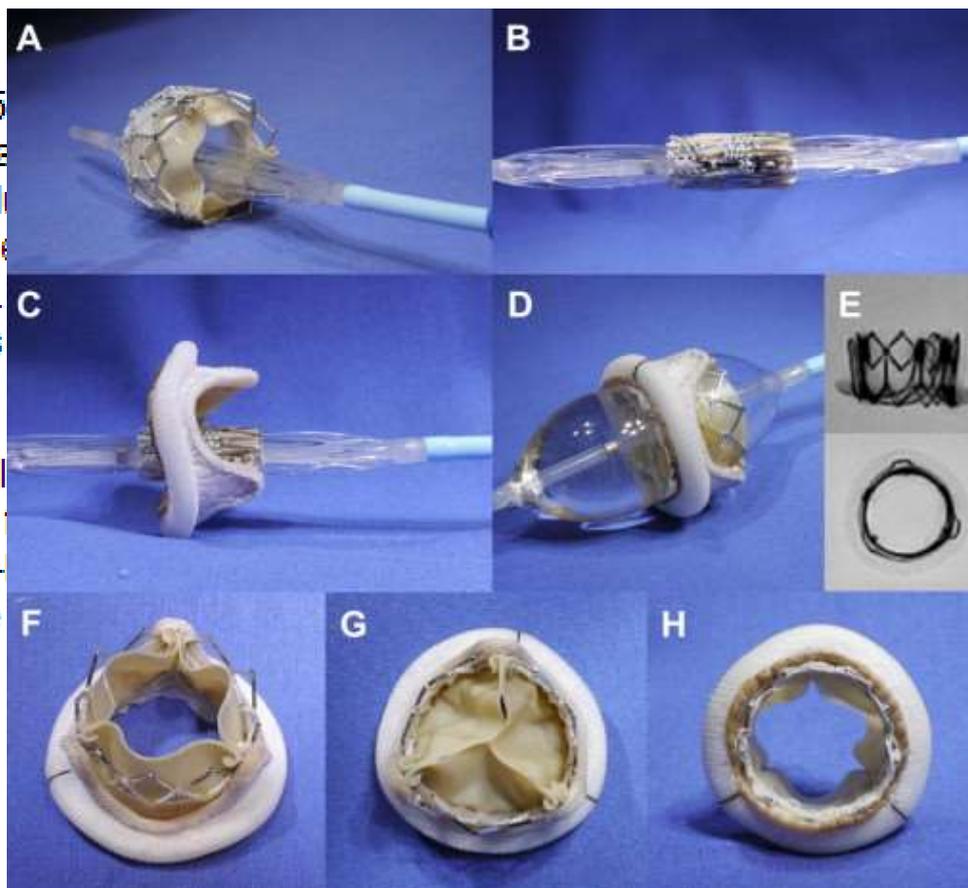
# Edwards Lifesciences

## Edwards' SAPIEN XT Valve Approved in Europe for Transcatheter Mitral and Aortic Valve-in-Valve Procedures

➤ currently, most of the reported series used Edwards SAPIEN balloon-expandable valve for TM VIV.

IRVINE, CA, February 05  
science of heart valves a  
for valve-in-valve proced  
treatment option for patie  
extreme risk for surgery.  
position, which address  
risk surgery.

"The European approval  
While this is not a large  
through a second open-  
Edwards' corporate vice



, the global leader in the  
received CE Mark in Europe  
providing a minimally invasive  
treatment, and who are at  
indication for the mitral  
be an alternative to a high-

is a milestone achievement.  
for patients unable to go  
" said Larry L. Wood,



**A device w/ only one chance!**

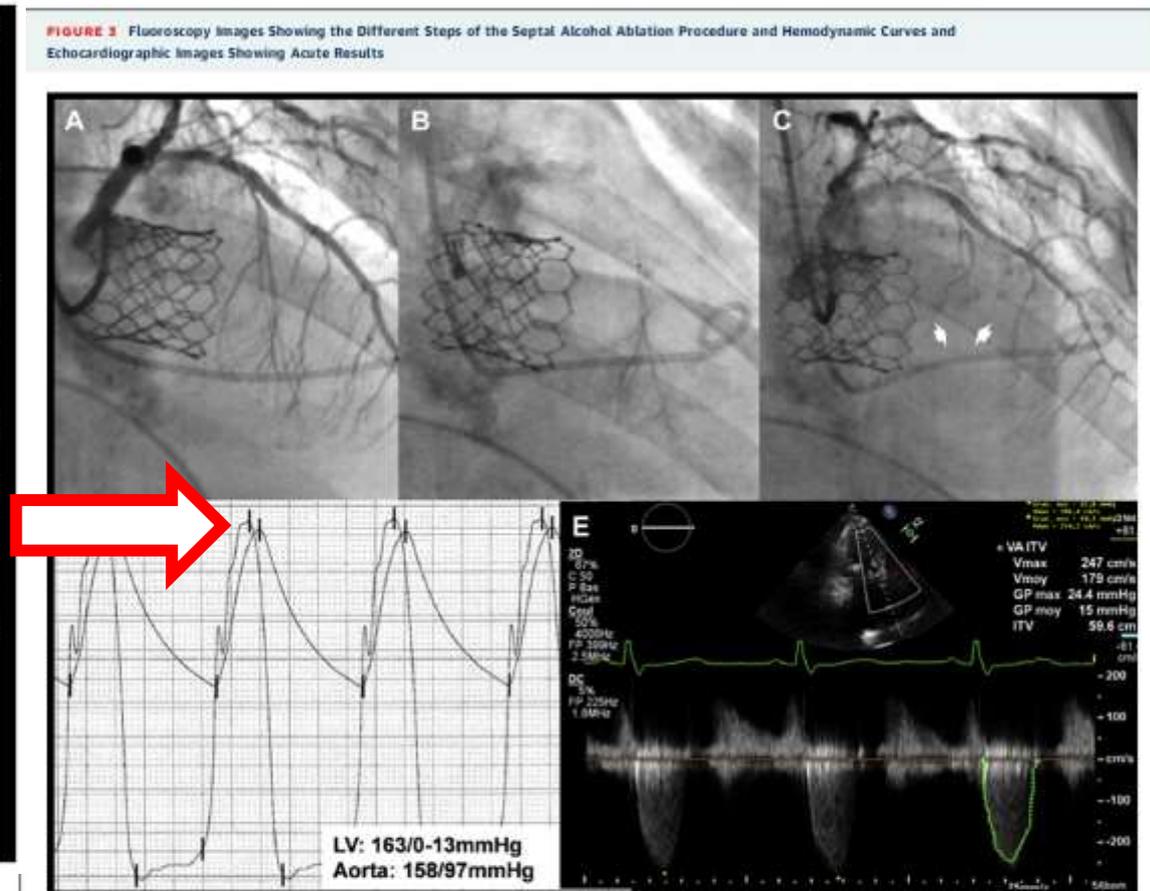
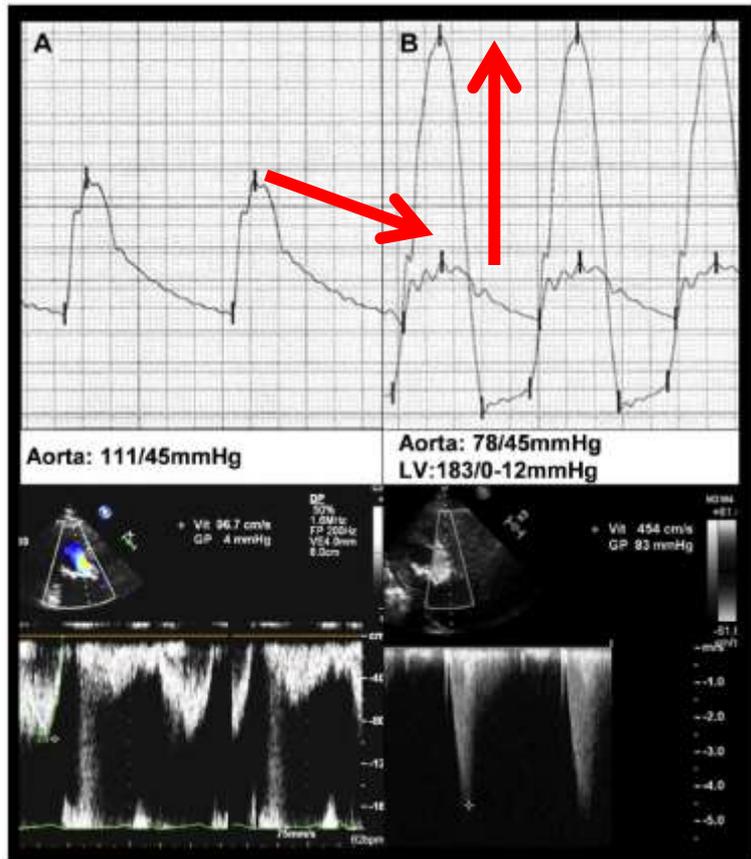
**Figure 4.** Transcatheter valve deployed within a surgical prosthesis (SAPIEN THV and Carpentier-Edwards). **A. Incorrect positioning.** The outflows of the surgical prosthesis and THV are superimposed. During balloon deployment, the prosthetic struts may be splayed, allowing the THV to embolize (as in Figure 5). **B. Correct positioning.** The THV overlaps the sewing ring of the surgical prosthesis, allowing more secure fixation.

## **Complications of transcatheter mitral VIV**

*Circulation.* 2010;121:1848-1857

# Bail-Out Alcohol Septal Ablation for Left Ventricular Outflow Tract Obstruction After Transcatheter Mitral Valve Replacement

## Complications of transcatheter mitral VIV

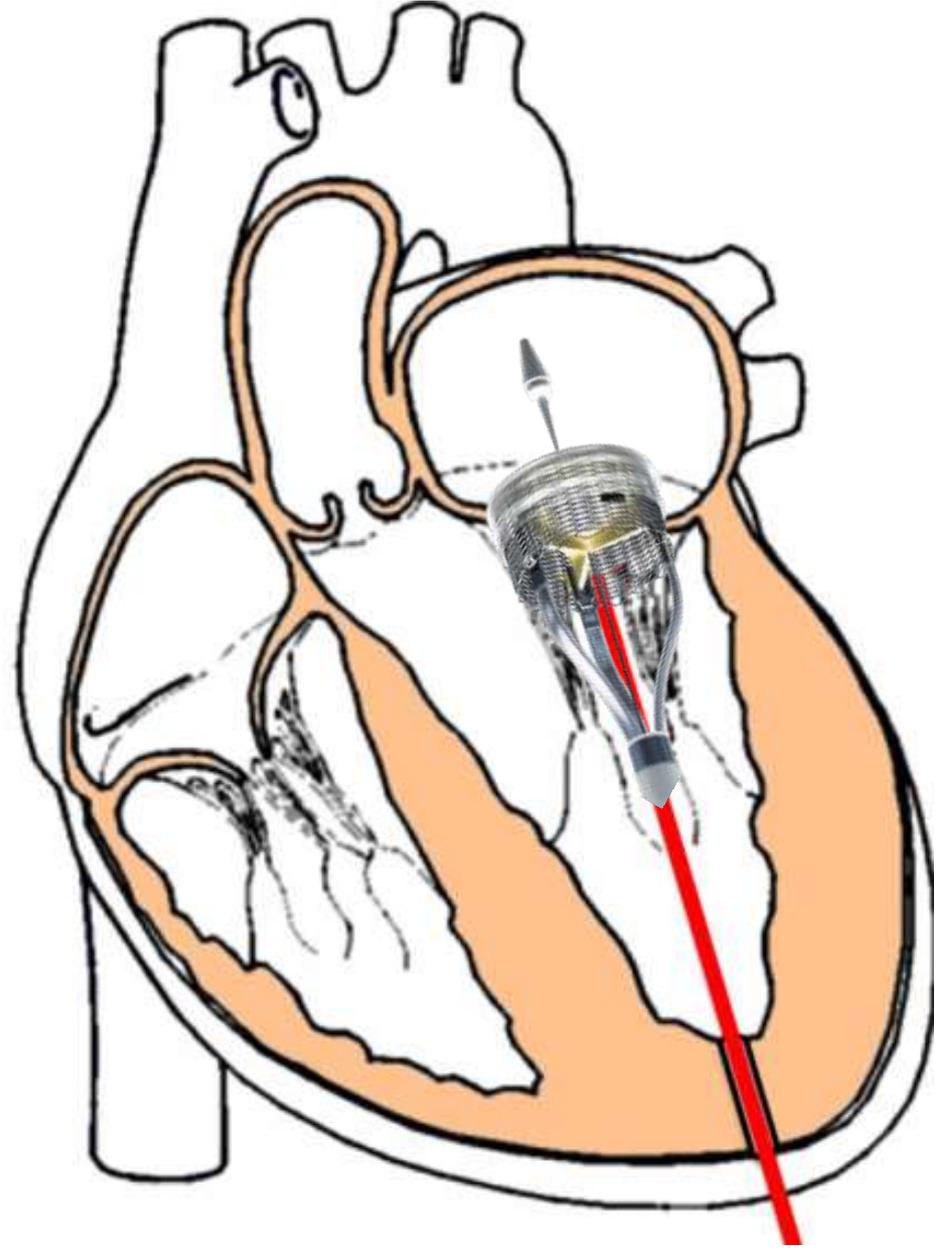


**(A)** A coronary angiogram confirmed the presence of a septal artery suitable for alcohol ablation. Two milliliters of pure ethanol were injected in the first septal branch **(B)**, with complete occlusion of the artery **(C, white arrows)**. **(D)** Immediately after injecting the ethanol, a normalization of the shape of the aorta pressure curve and recovery of the pressure were observed. **(E)** Echocardiographic assessment confirmed the maximal left ventricular outflow gradient of 24 mm Hg (Online Video 4), LV = left ventricle.

**(A)** Before implantation of the prosthesis, the aortic pressure was 111/45 mm Hg, the shape of the aortic pressure wave was normal, and there was not a significant gradient at the LVOT. **(B)** Immediately after implantation of the prosthesis, the aortic pressure decreased to 78/45, the shape of the aortic pressure wave changed to a spiky-and-dome pattern, and the maximal LVOT gradient was >100 mm Hg (Online Video 2 and 3). LV = left ventricle; LVOT = left ventricular outflow tract.

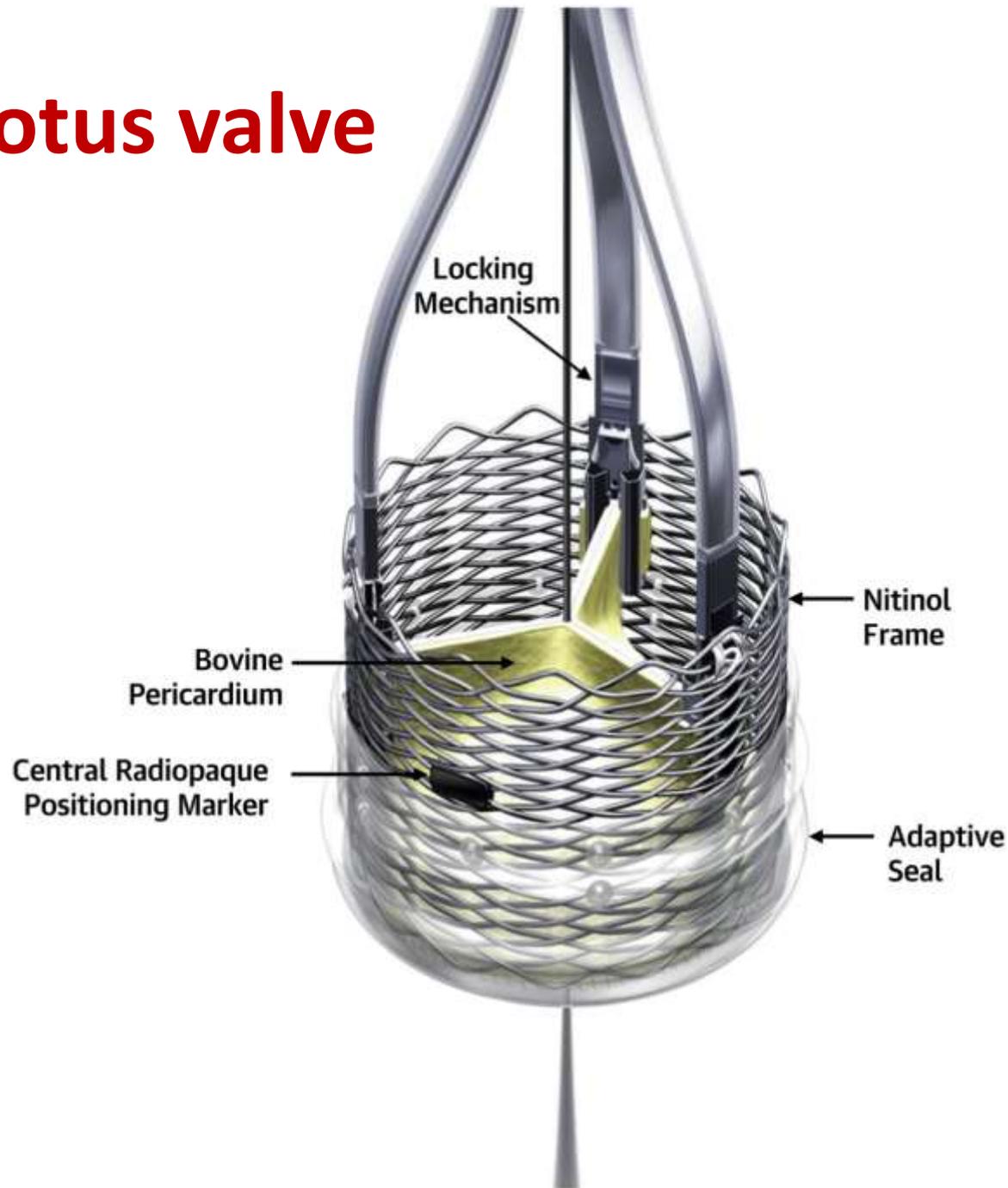
# Transcatheter VIV for failed mitral bioprosthesis

- **Recently, the mechanically expanded Lotus valve has also been successfully used for TM VIV.**

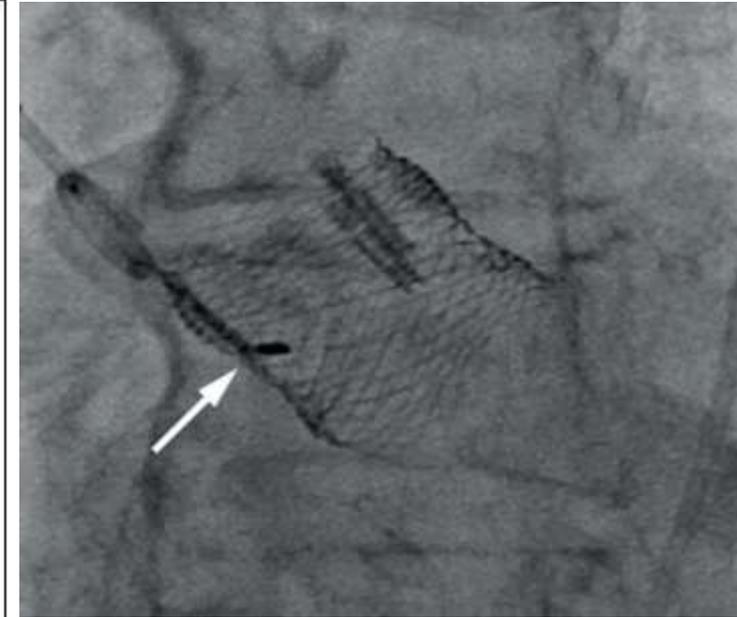
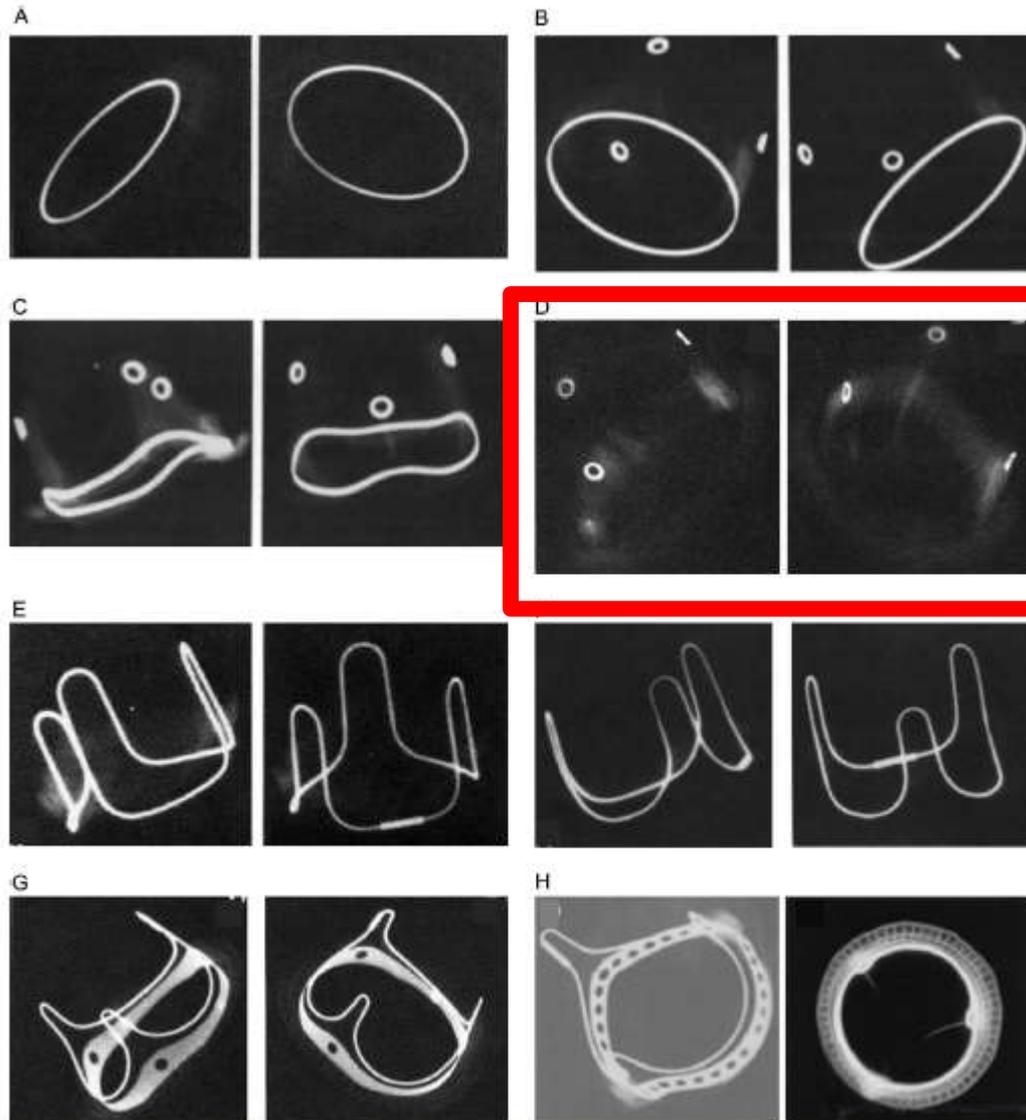


# The beauty of Lotus valve

- **The Lotus Valve is repositionable and fully retrievable.**
- **It was designed to facilitate accurate primary positioning, early valve function, and hemodynamic stability during deployment reduce paravalvular leaks**



# Radiographic appearance of stented bioprosthesis



**The waist will  
tell you where  
the Lotus is !**

Figure 5. Radiographic Appearances of Various Stented Bioprosthetic Valves

# F 79, presented with progressive dyspnea for 6 months, Fc III-IV



- Rheumatic heart disease s/p redo AVR (Edwards SAV porcine 21mm), MVR (Edwards porcine 31mm) and TVA 8 years ago
- Chronic atrial fib, Chronic kidney disease stage 3, Old pulmonary TB
- Logistic Euroscore: 50%

# TEE



**Preserved LV & RV systolic function.**

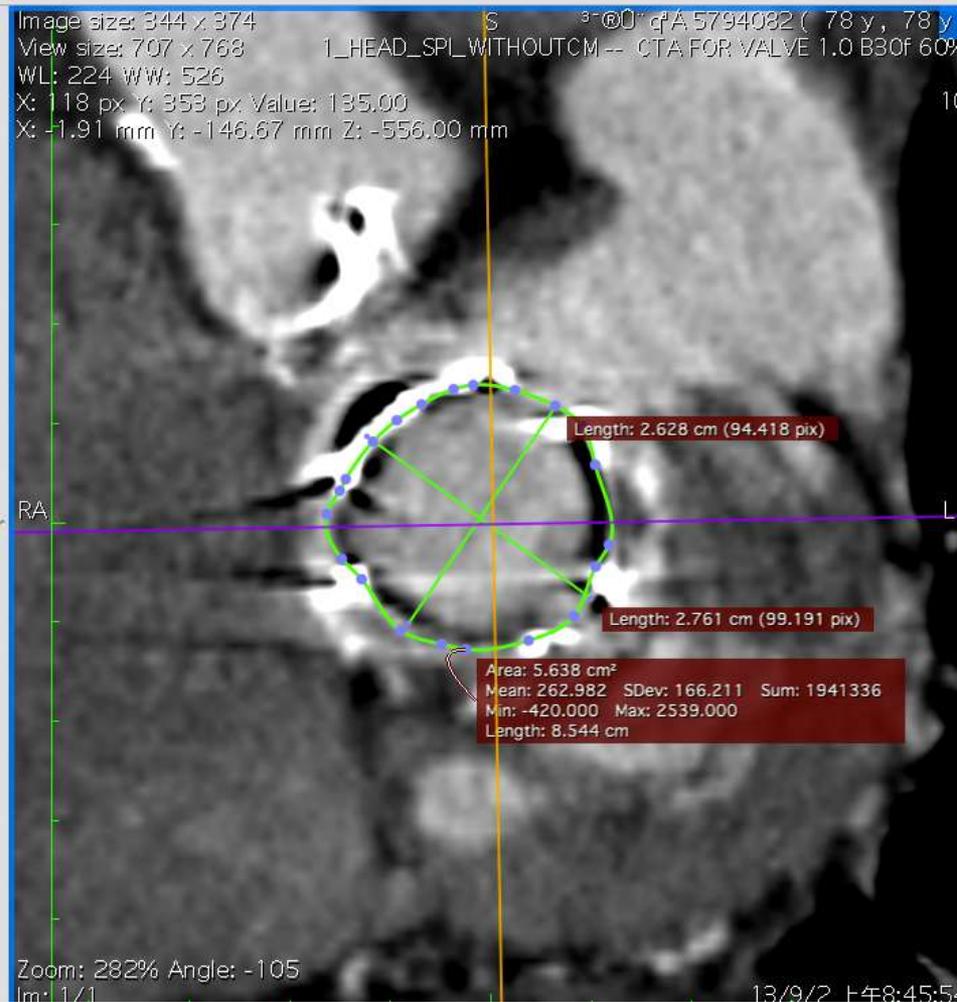
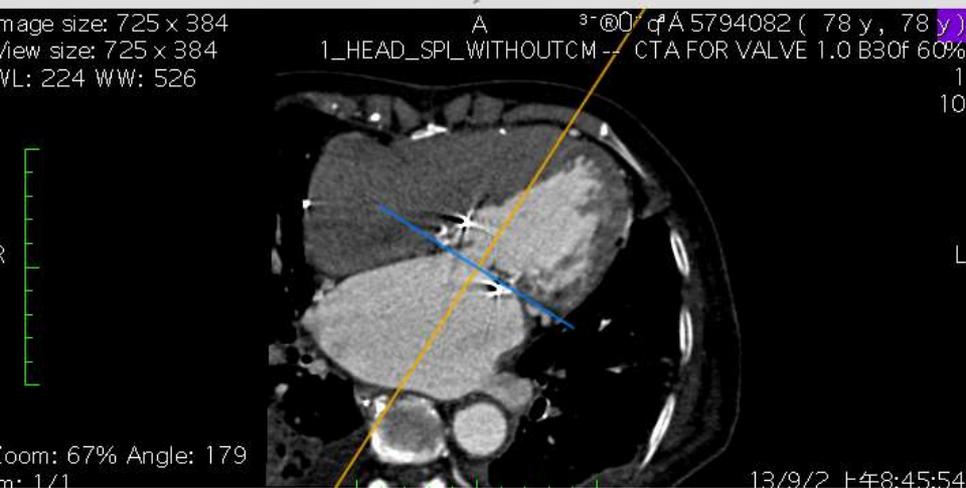
**AV: Prosthetic: 8 mmHg MPG, 24 mmHg PPG.**

**MV: Prosthetic: 9 mmHg MPG, 20 mmHg PPG, MVA= 3.1 cm<sup>2</sup> by PHT.**

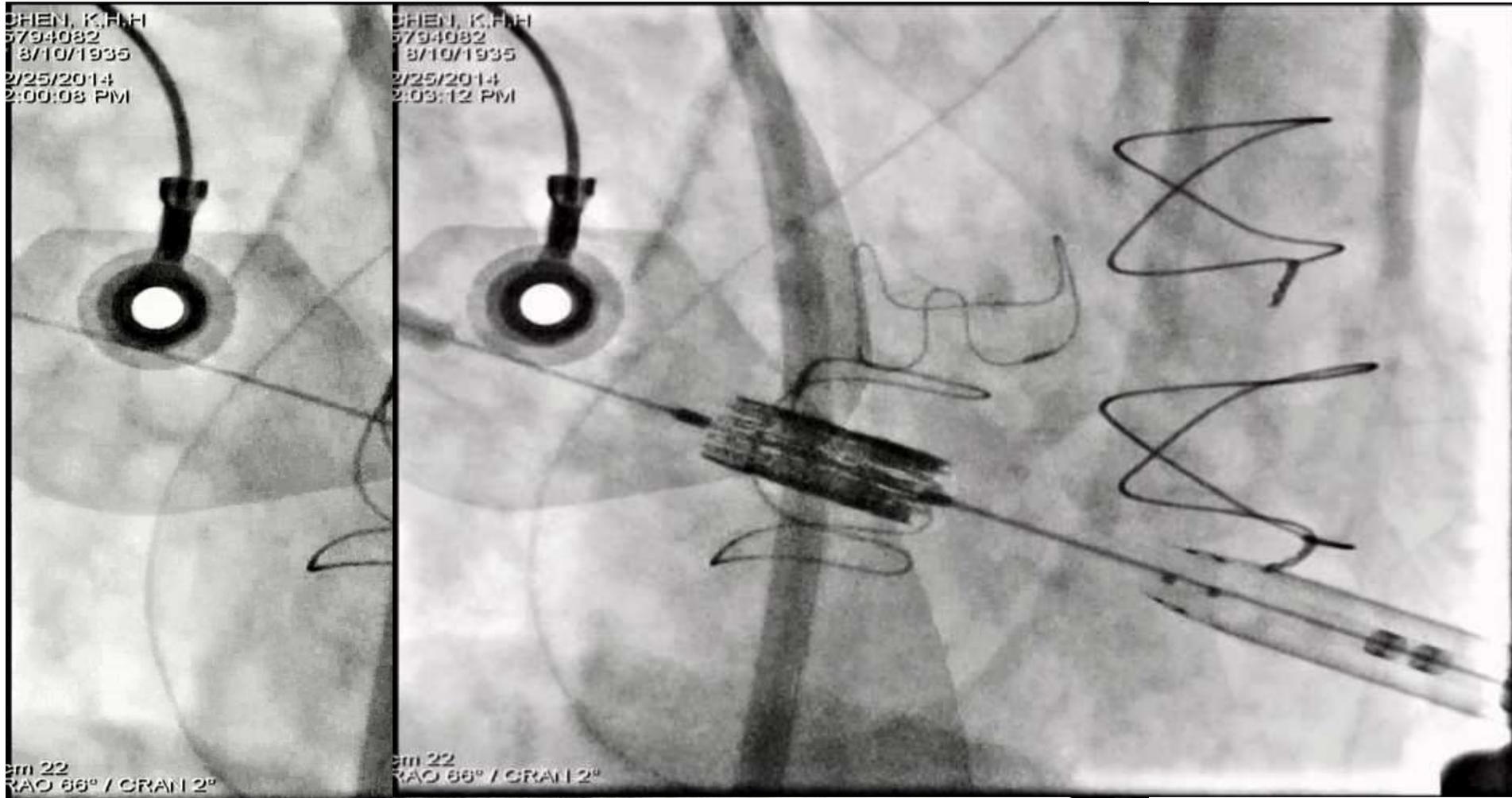
**MR: Severe, TV: Repaired but with TR: Severe, RVSP= 42 mmHg. PR: Mild.**

# Inner diameter of mitral bioprosthesis

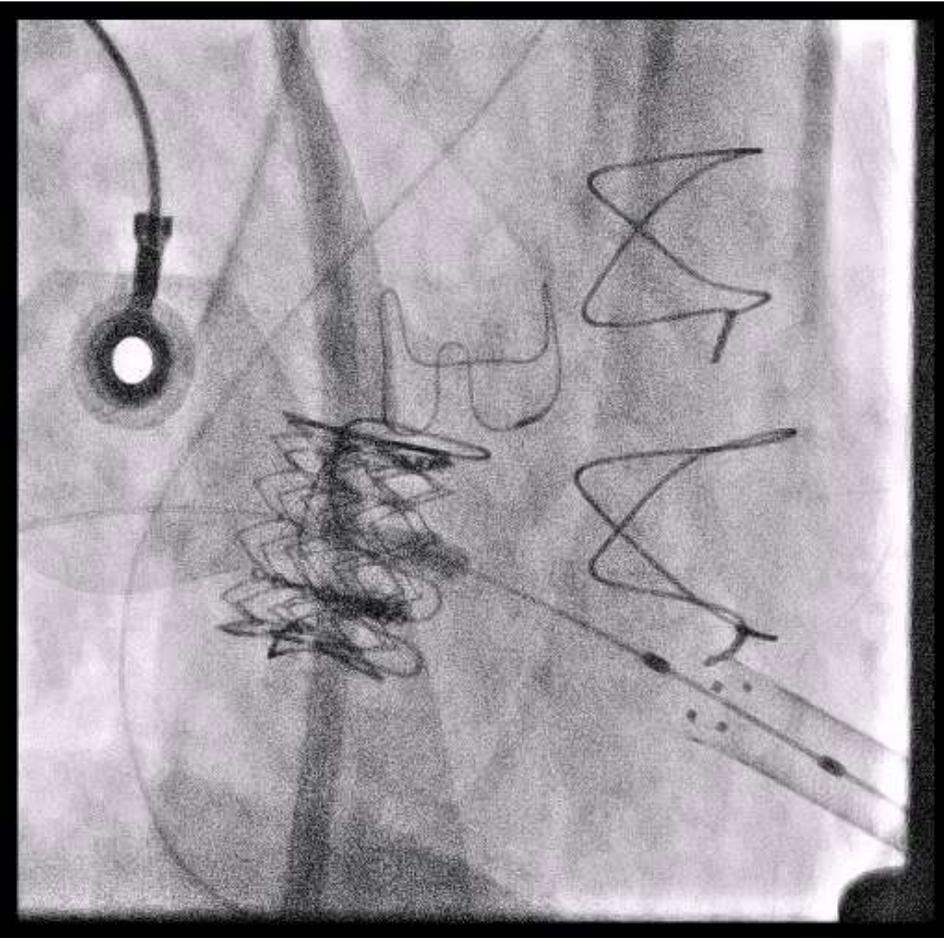
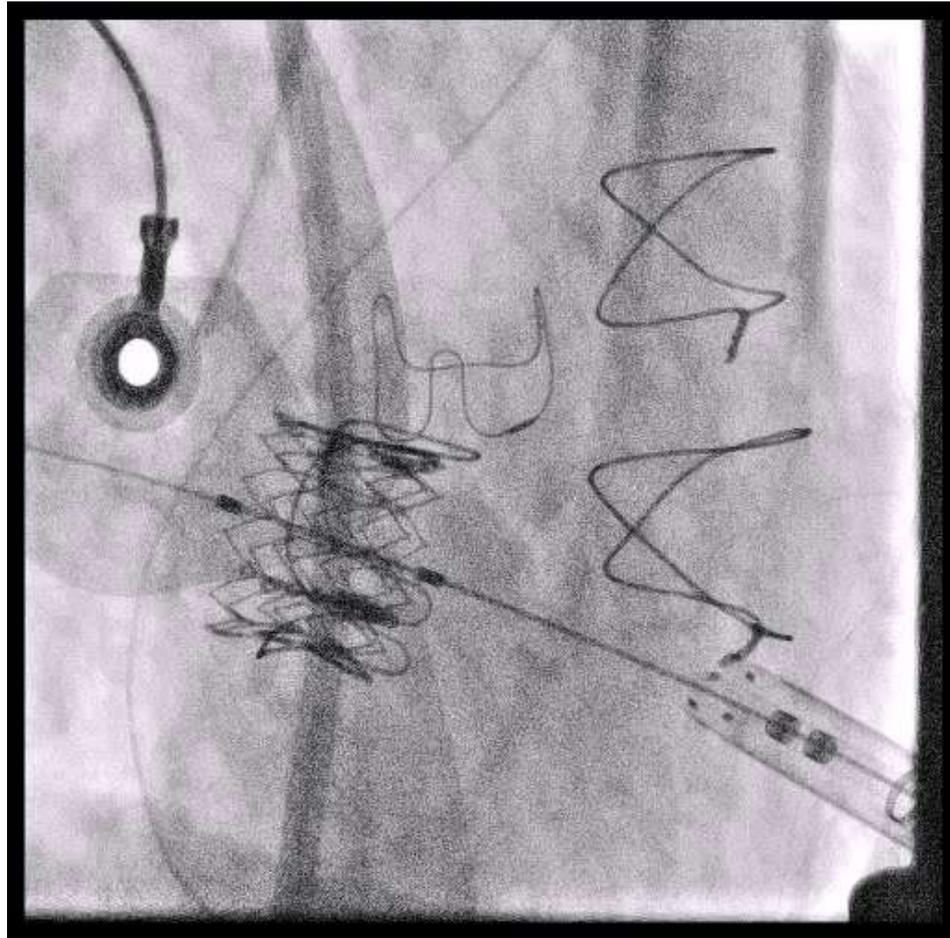
## 27mm



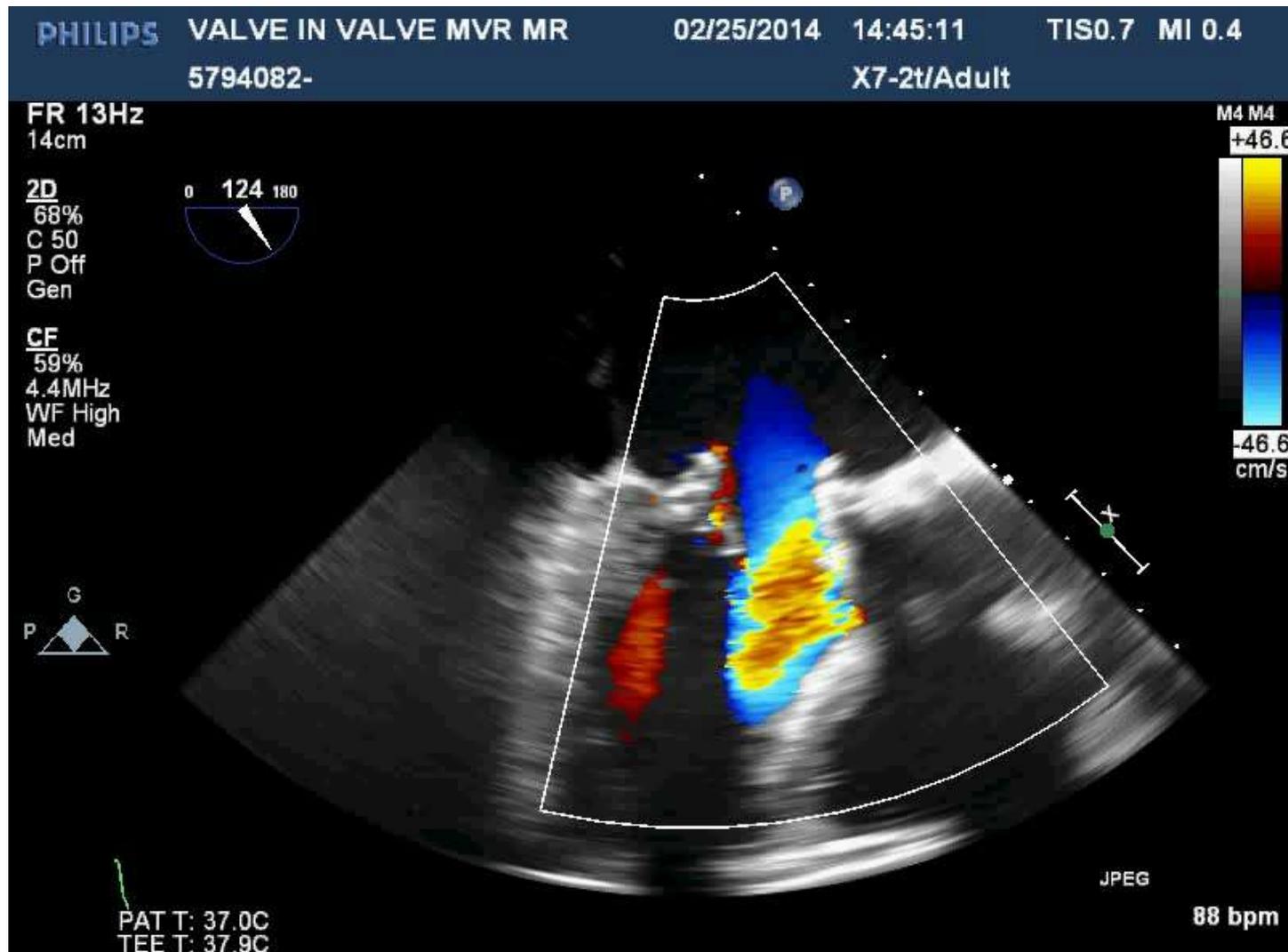
# Transapical approach with an Ascendra 3 introducer and a 29mm Sapien XT



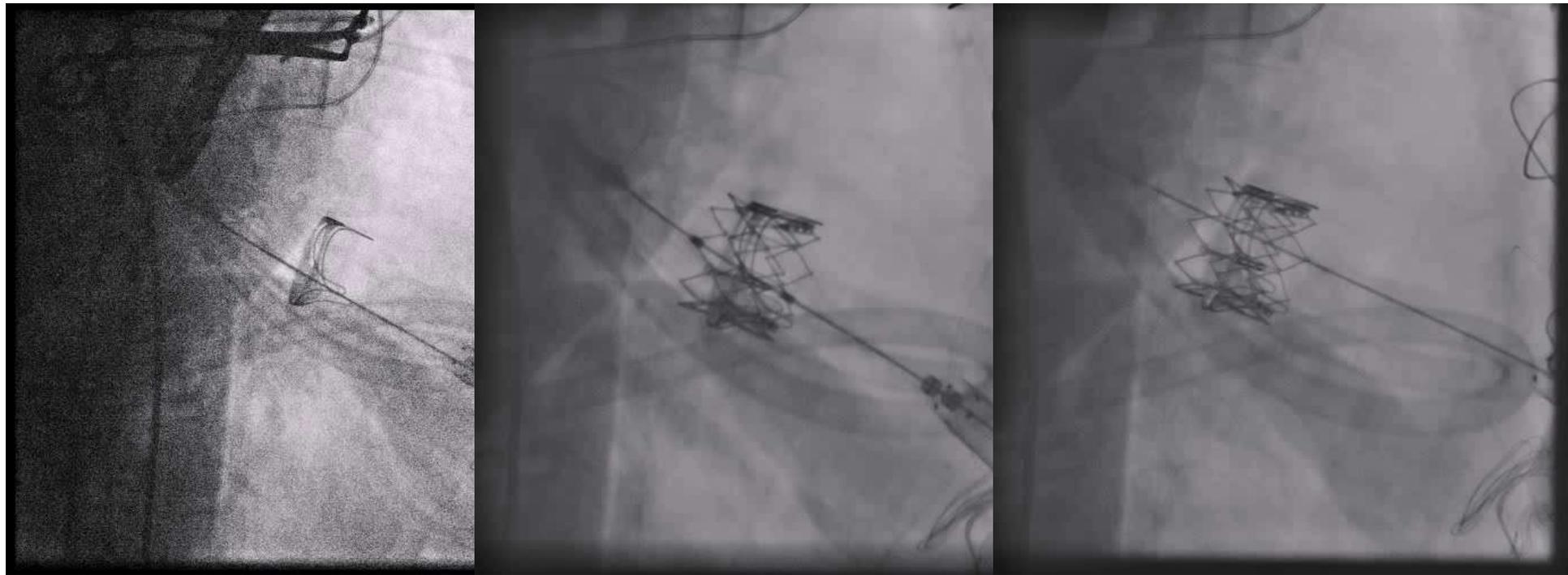
# Transapical implantation of Sapien XT



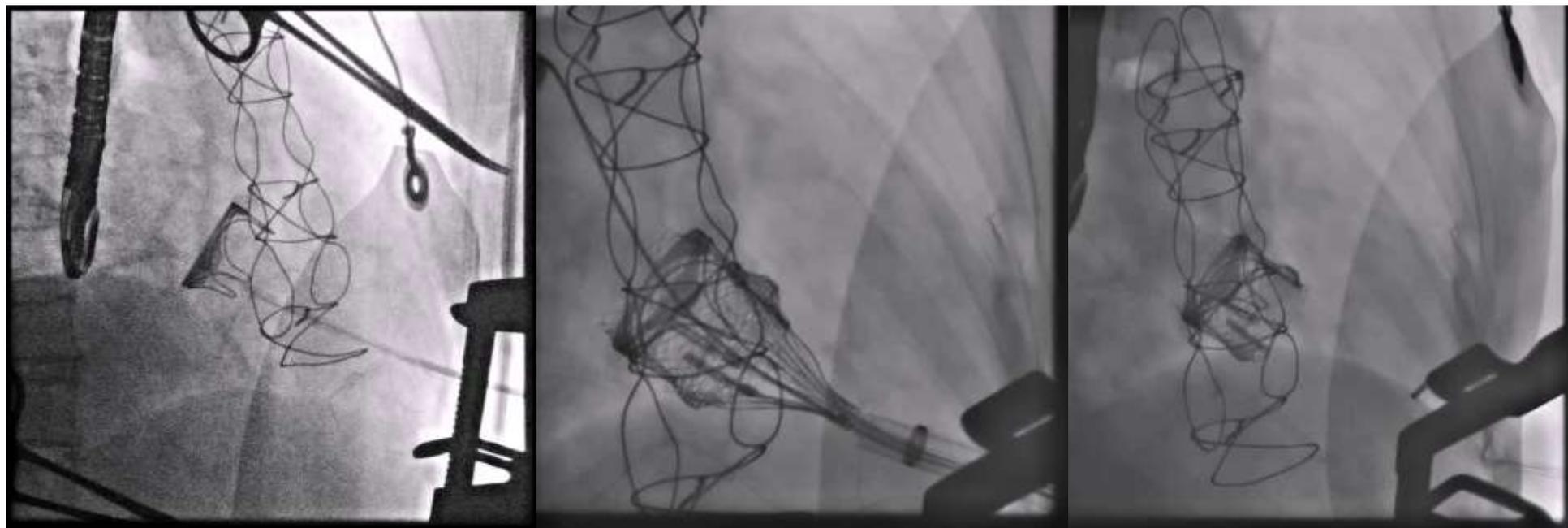
# TEE after implantation of Sapien XT



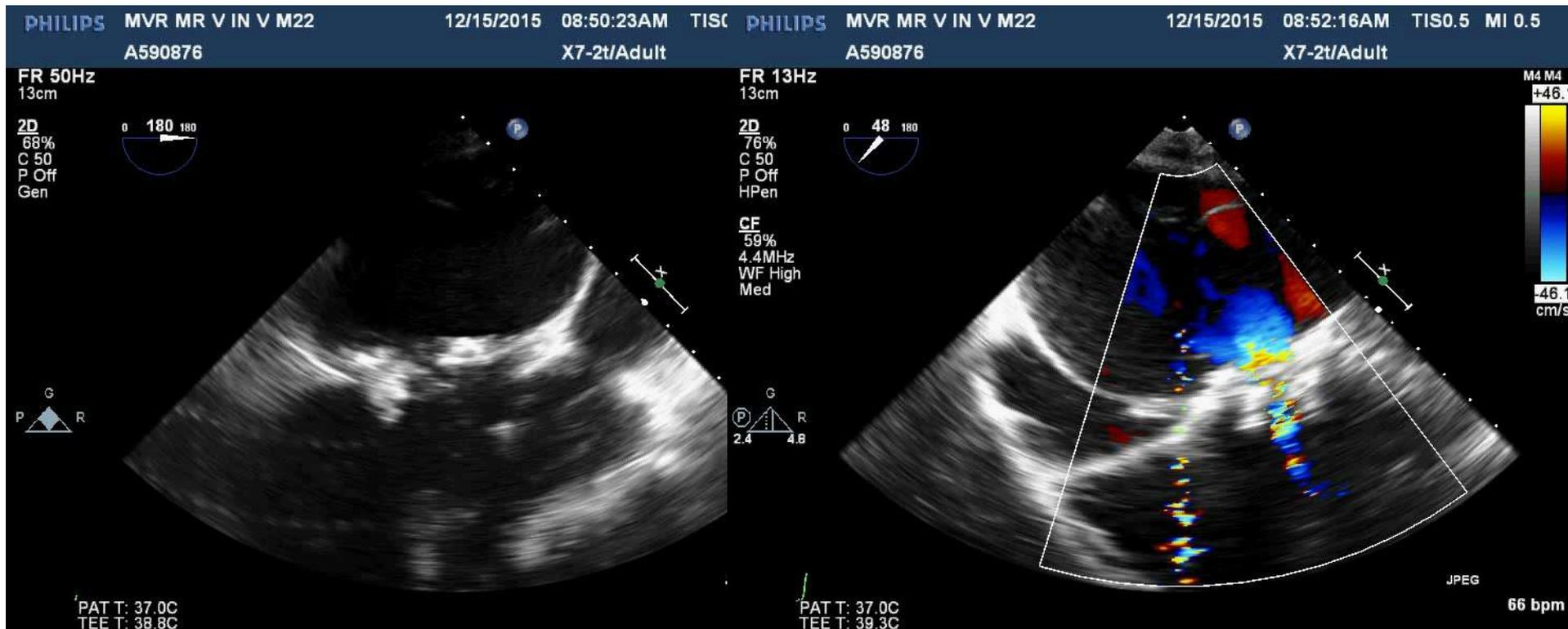
**M 82, presented with progressive dyspnea  
for 4 months, Fc III-IV**



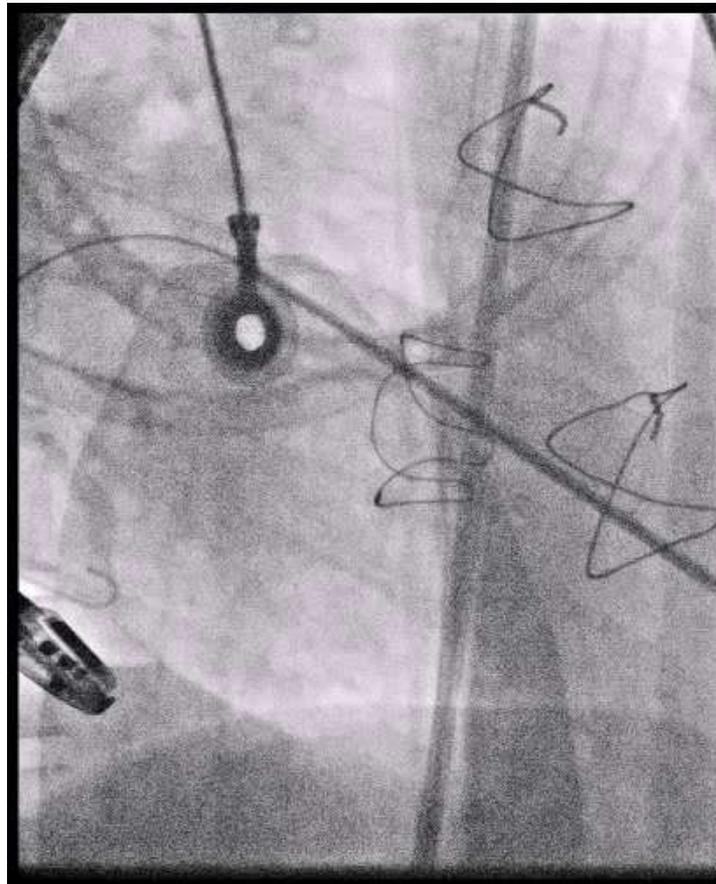
**M 82, presented with progressive dyspnea  
for 4 months, Fc III-IV  
Treated with Lotus system**



# F 78, presented with progressive dyspnea for 3 months, Fc III-IV



# Wiring



**PHILIPS** MVR MR V IN V M2 12/15/2015 09:57:23AM TIS0.1 MI 0.5  
A590876 X7-2t/Adult

FR 50Hz  
12cm

**2D**  
78%  
C 50  
P Off  
Gen

0 80 180

G  
P R

JPEG

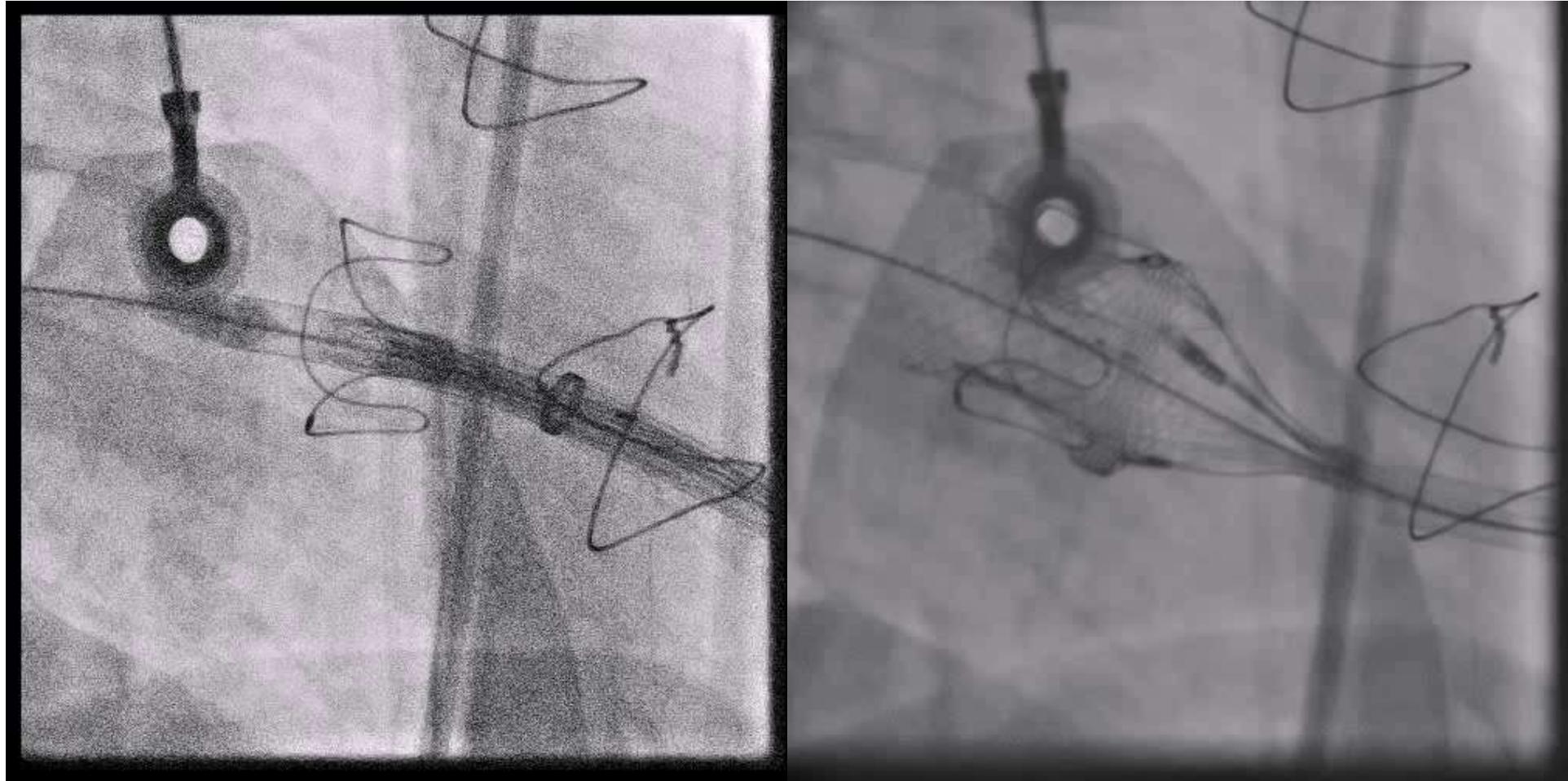
PAT T: 37.0C  
TEE T: 38.8C

75 bpm

M4

A Transesophageal Echocardiography (TEE) image showing a cross-section of the heart. A catheter tip is visible, and a measurement line is drawn across the image. The image is labeled 'M4' and 'JPEG'.

**Positioned a little high in LA**

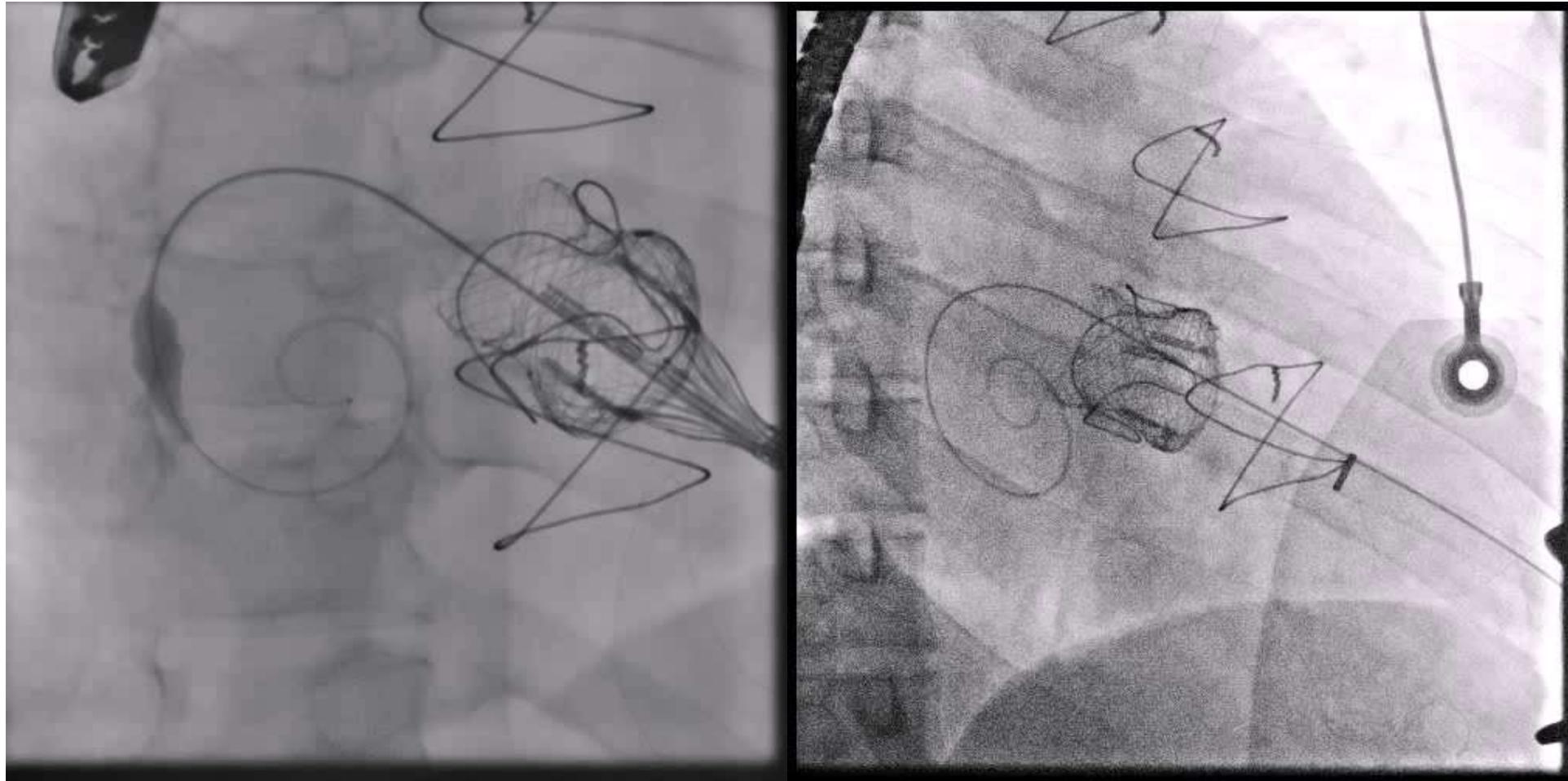


# Positioned a little high in LA

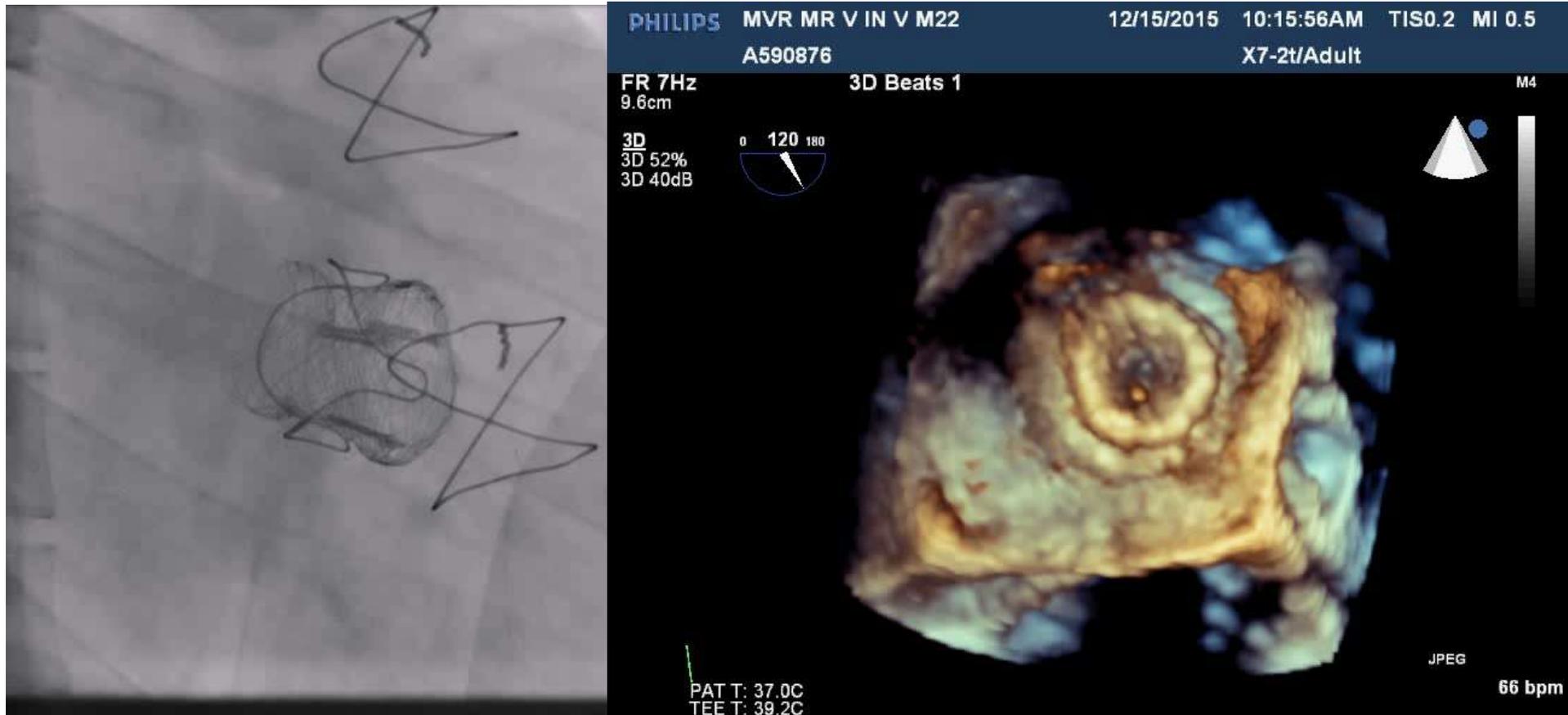


v in v\_A5

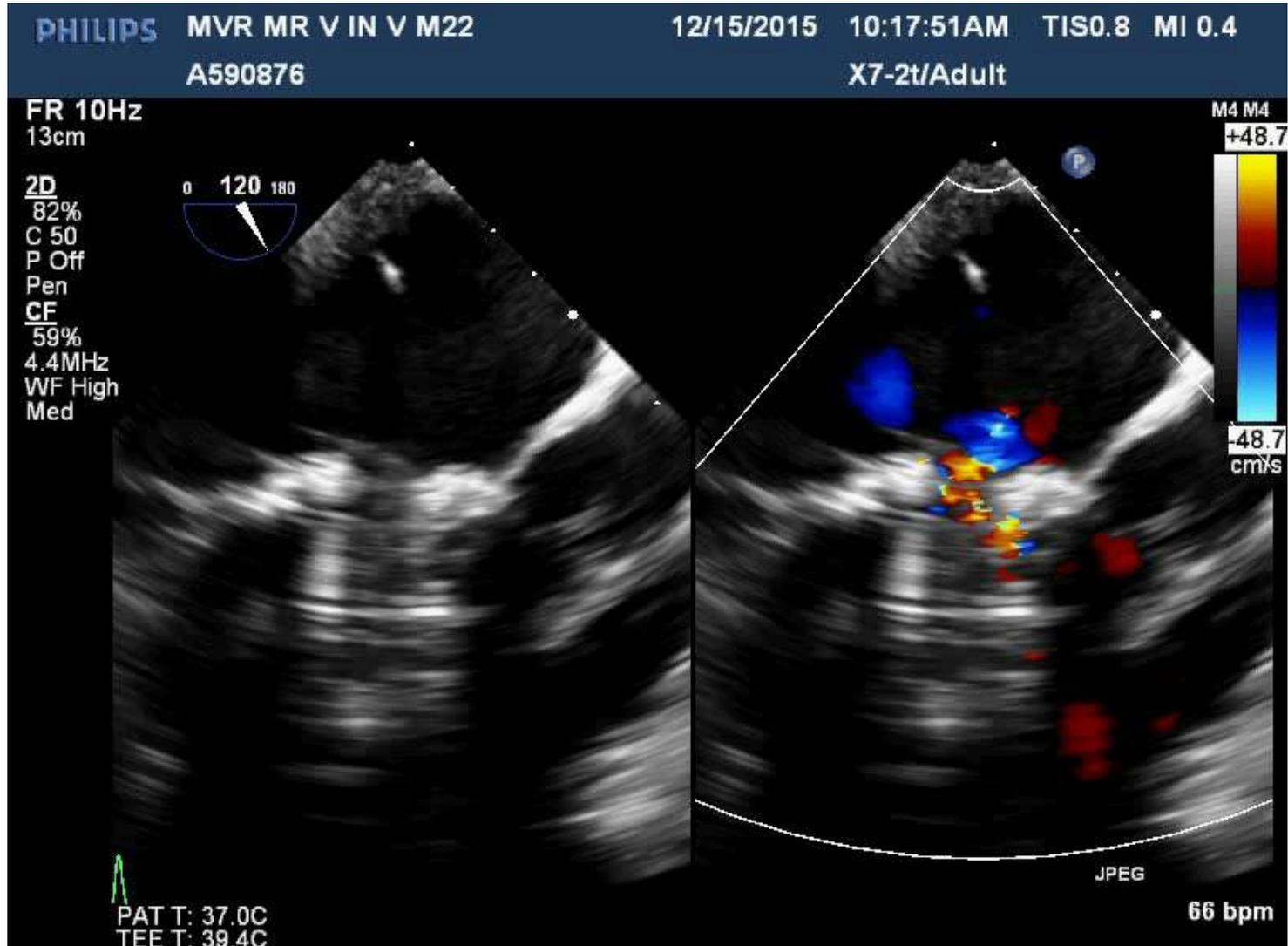
# Re-sheathing and re-positioning



# After final releasing with en face view



# Final results



# Conclusions

- Valve-in-valve (VIV) implantation can be considered as **an acceptable alternative** to re-do open heart surgery for elderly high-risk surgical patients with bioprosthetic degeneration.
- **Proper sizing, selection of appropriate devices, and precise implantation depth** are the keys to success in transcatheter VIV procedures.
- The Lotus Valve has the advantages of being repositionable and fully retrievable.
- However, longer term follow-up and head-to-head comparisons will be needed to establish **the true role of VIV implantation for dysfunctional bioprosthesis** and **the roles of different devices for this application.**