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Sheraton Grande Walkerhill Hotel, Seoul, Korea

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

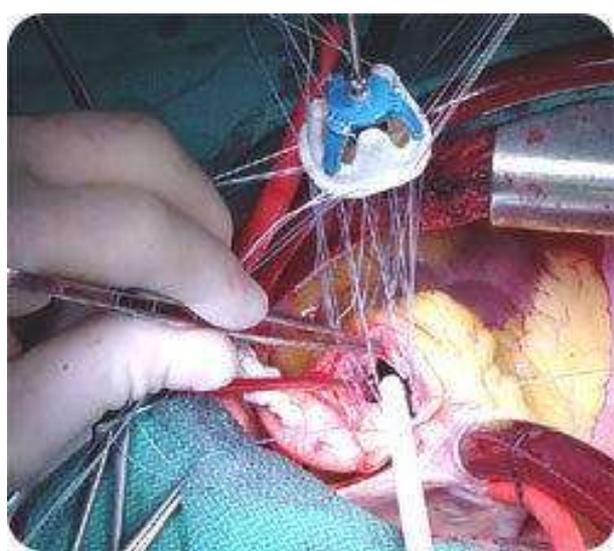


Wei-Hsian Yin, MD, PhD, FESC, FAPSC.

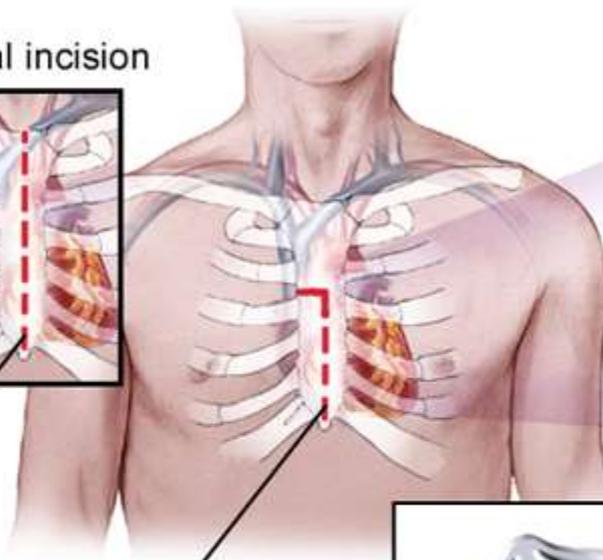
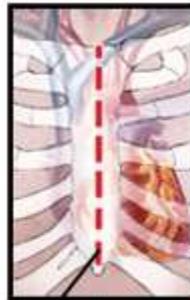
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Valve-in-valve Implantation for failed Bioprostheses: a new frontier of TAVI

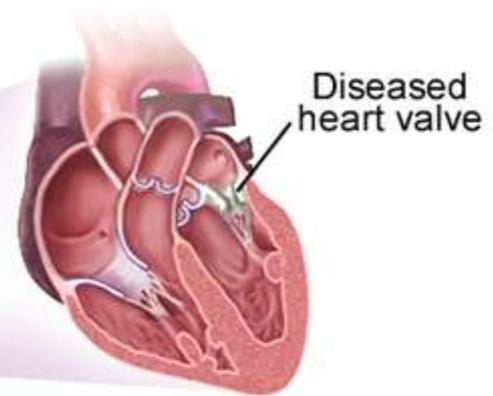
- The clinical use of bioprosthetic valves in the treatment of valvular heart disease has been growing during the past 2 decades.



Typical incision

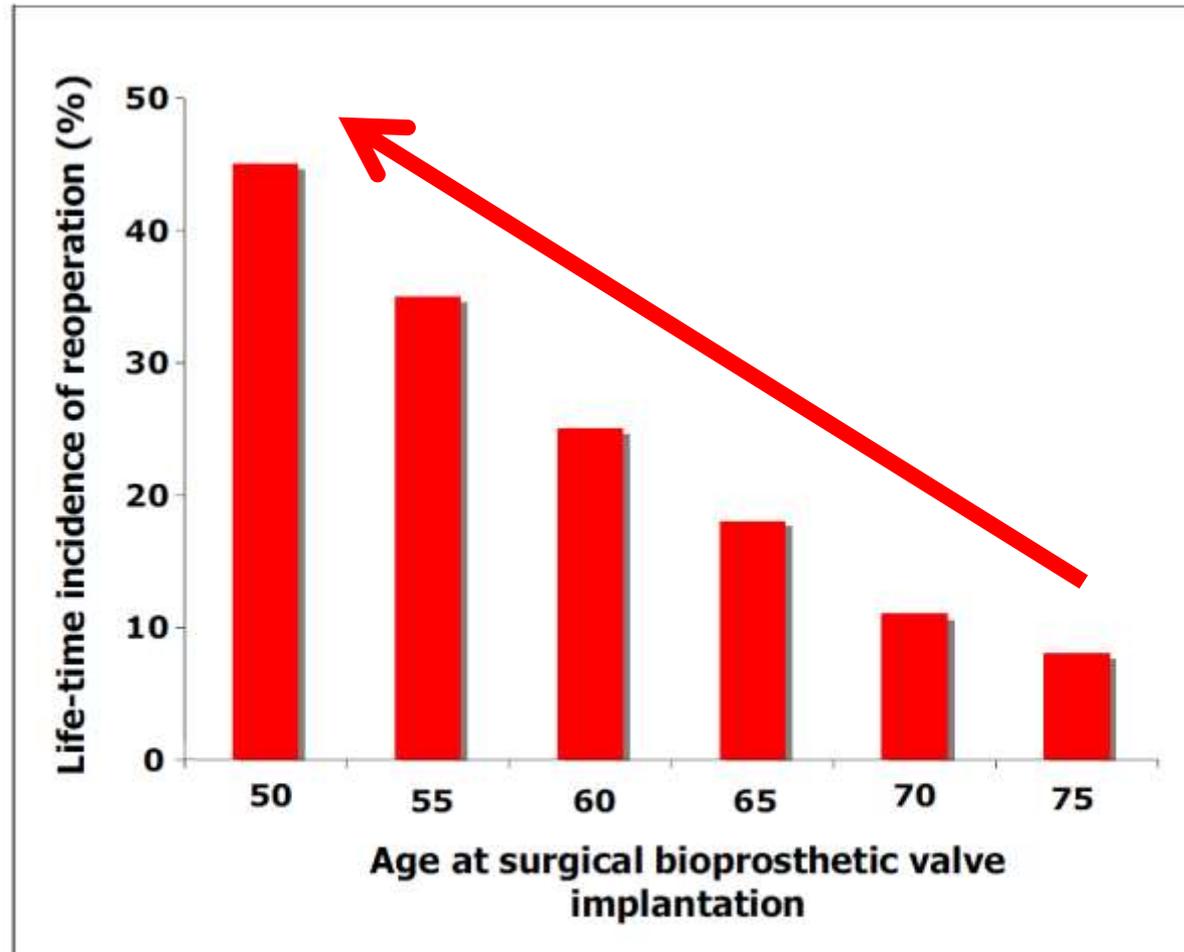


Incision for minimally invasive heart valve surgery



- 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

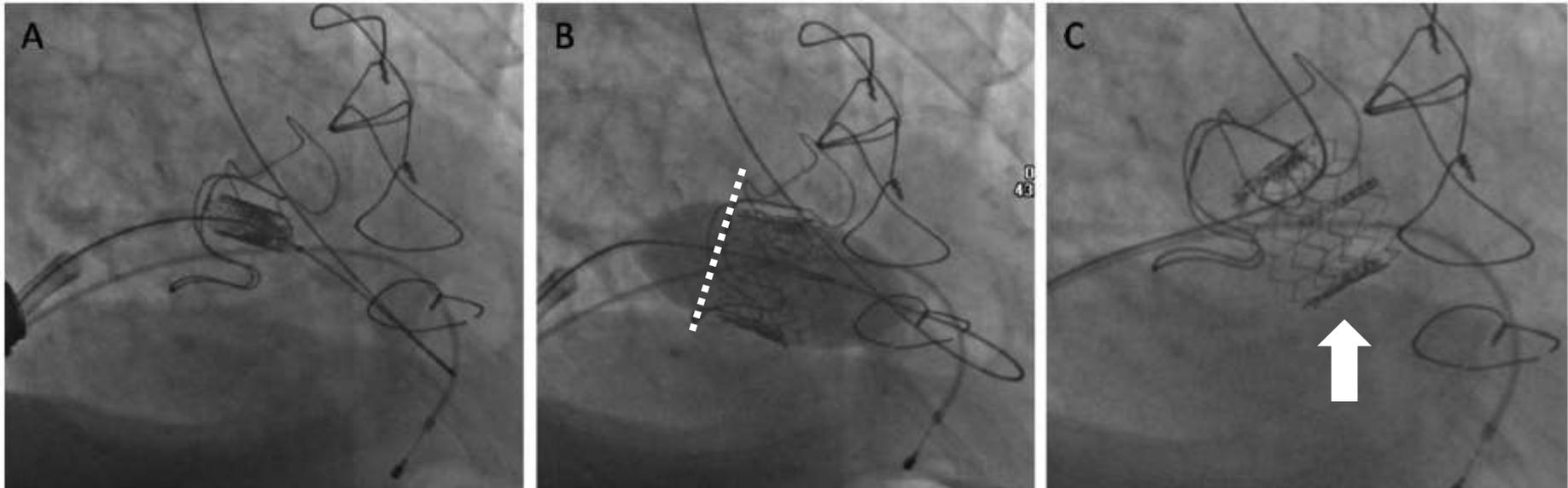


Thrombus

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†

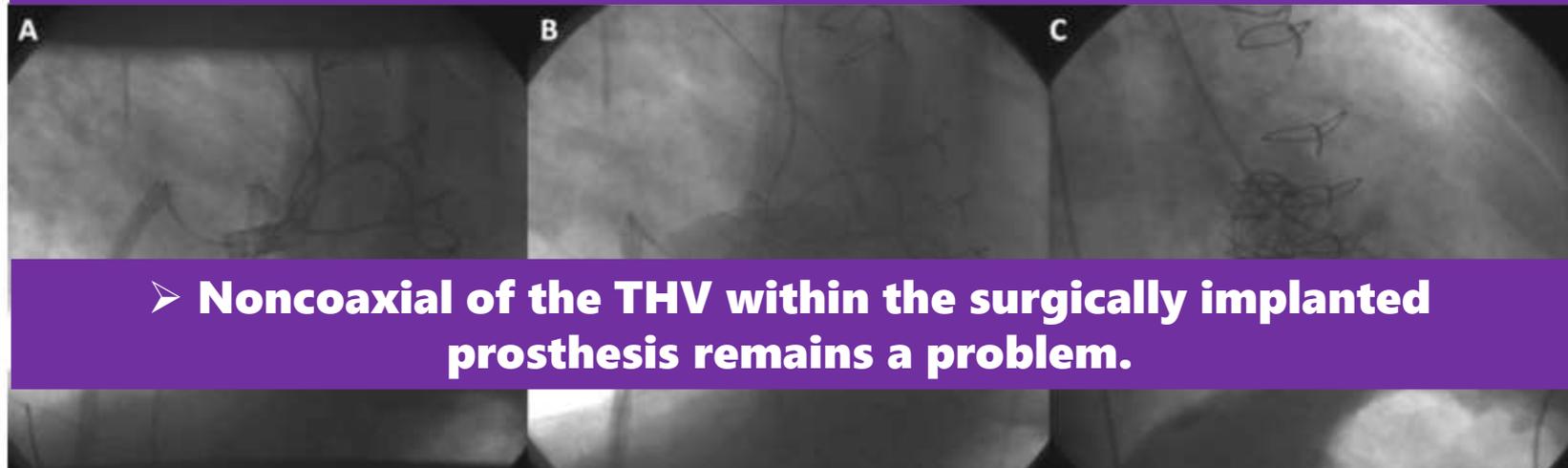
- **After that, all 5 subsequent implantations were successfully performed with transapical access.**

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

Transvenous access

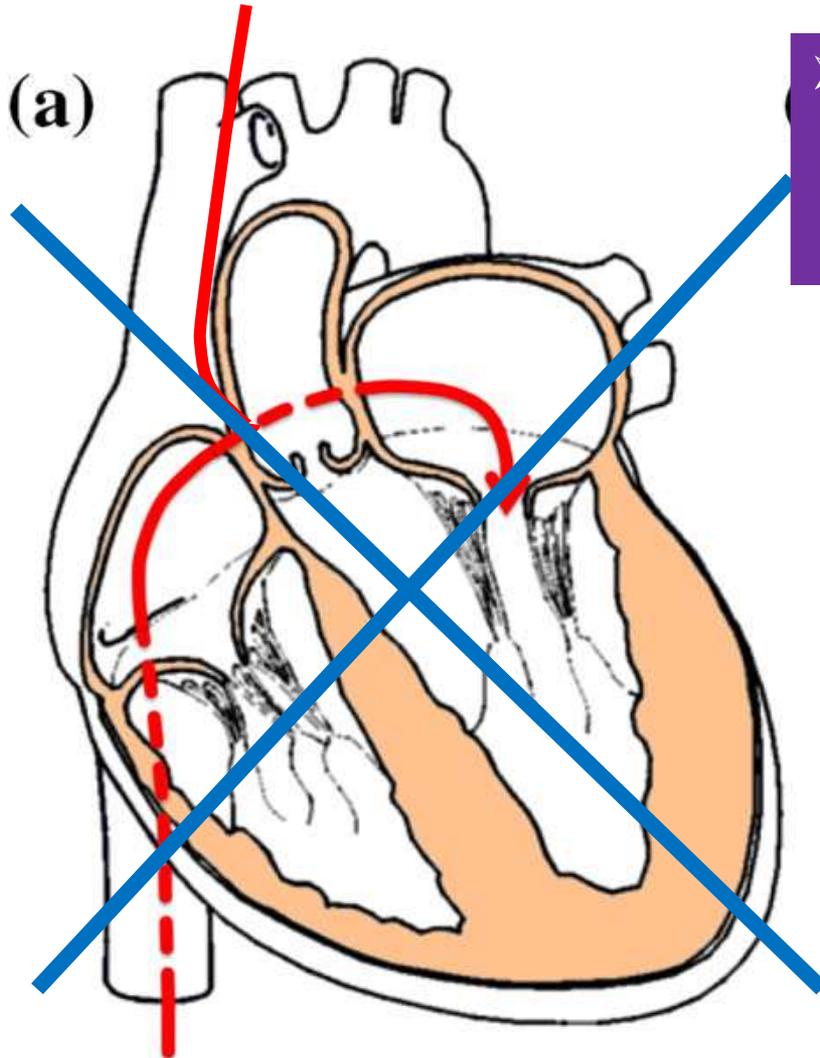


➤ **The procedure is time-consuming and carries a higher risk.**

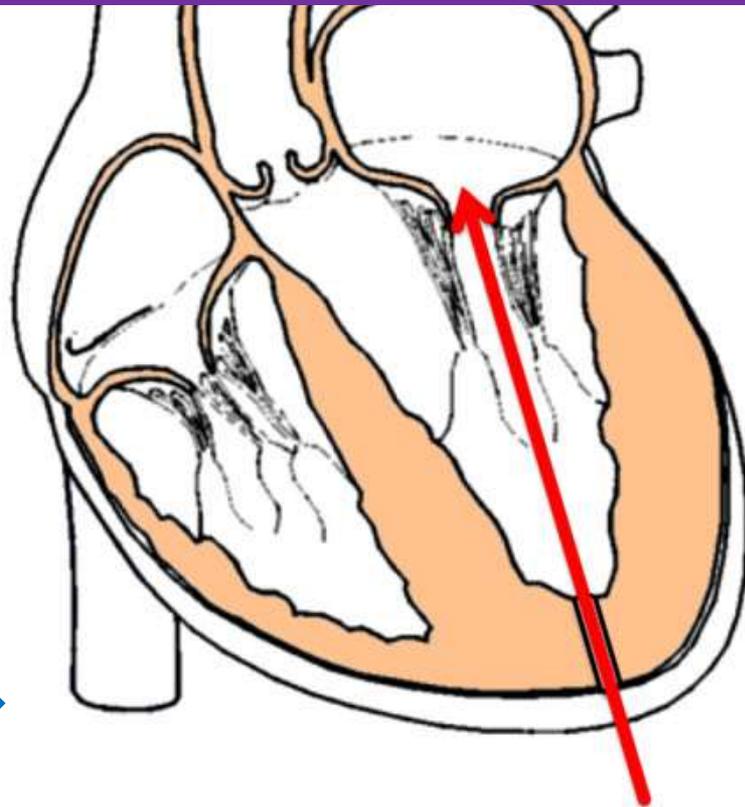


➤ **Noncoaxial of the THV within the surgically implanted prosthesis remains a problem.**

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.





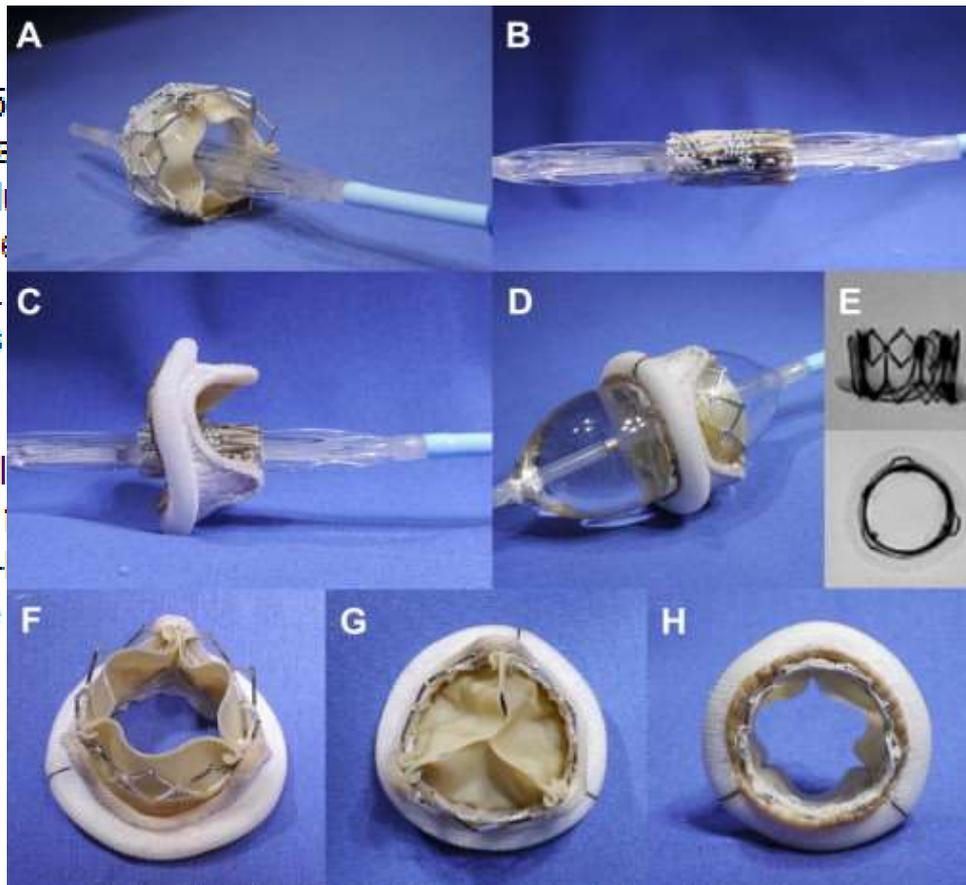
Edwards Lifesciences

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!

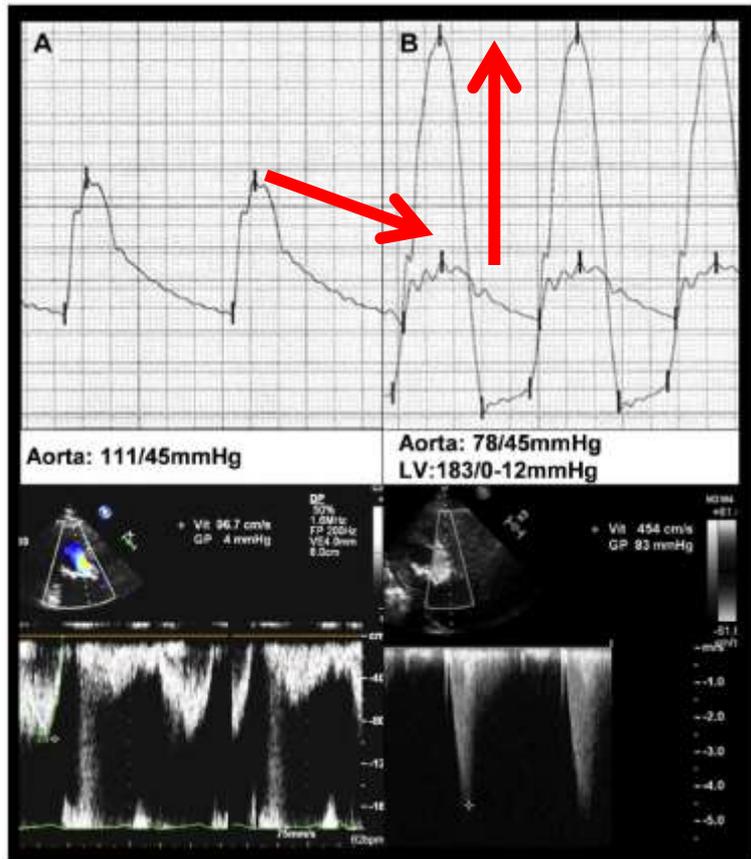
Figure 4. Transcatheter valve deployed within a surgical prosthesis (SAPIEN THV and Carpentier-Edwards). **A. Incorrect positioning.** The outflows of the surgical prosthesis and THV are superimposed. During balloon deployment, the prosthetic struts may be splayed, allowing the THV to embolize (as in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

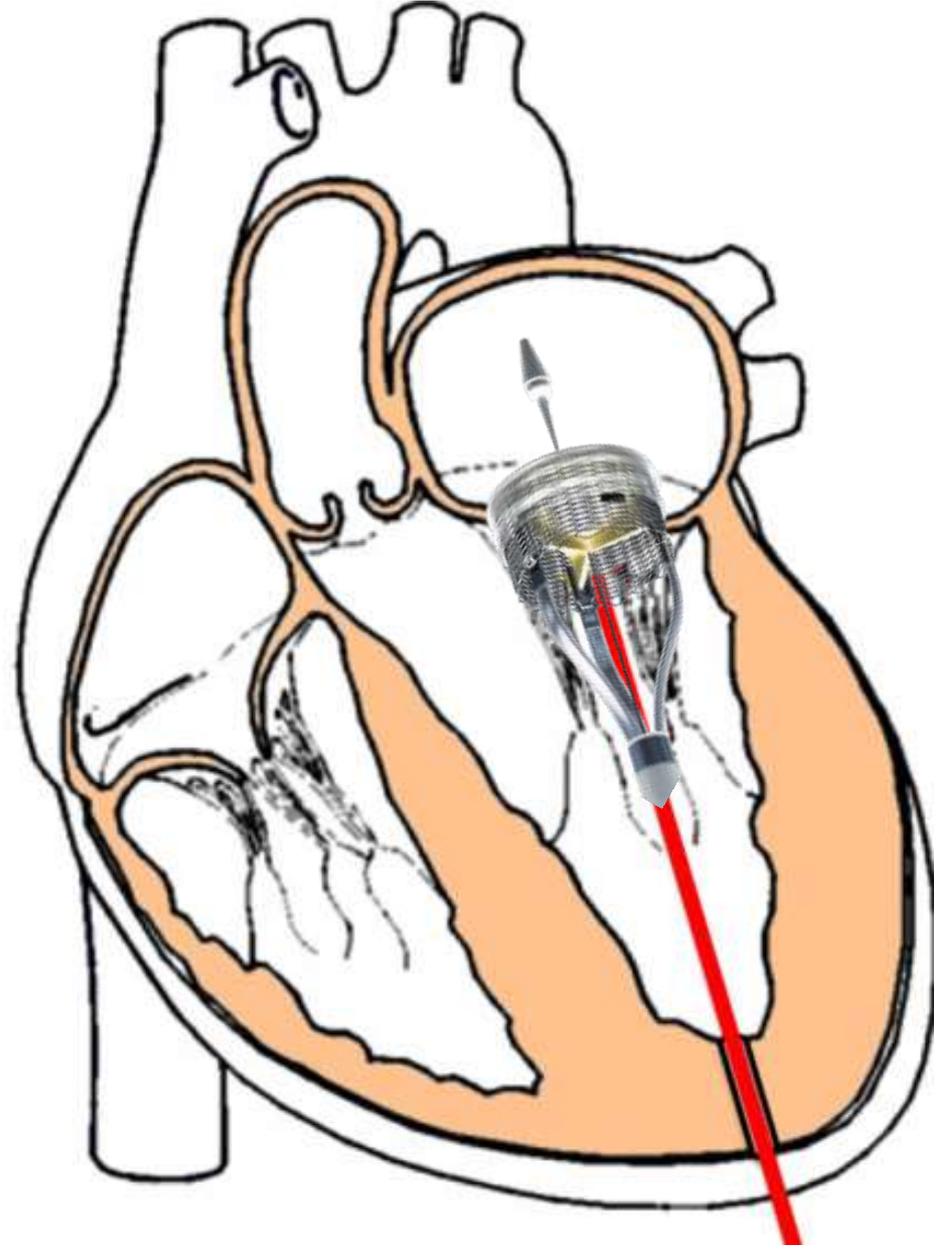
FIGURE 3 Fluoroscopy Images Showing the Different Steps of the Septal Alcohol Ablation Procedure and Hemodynamic Curves and Echocardiographic Images Showing Acute Results



(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 aortic 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.

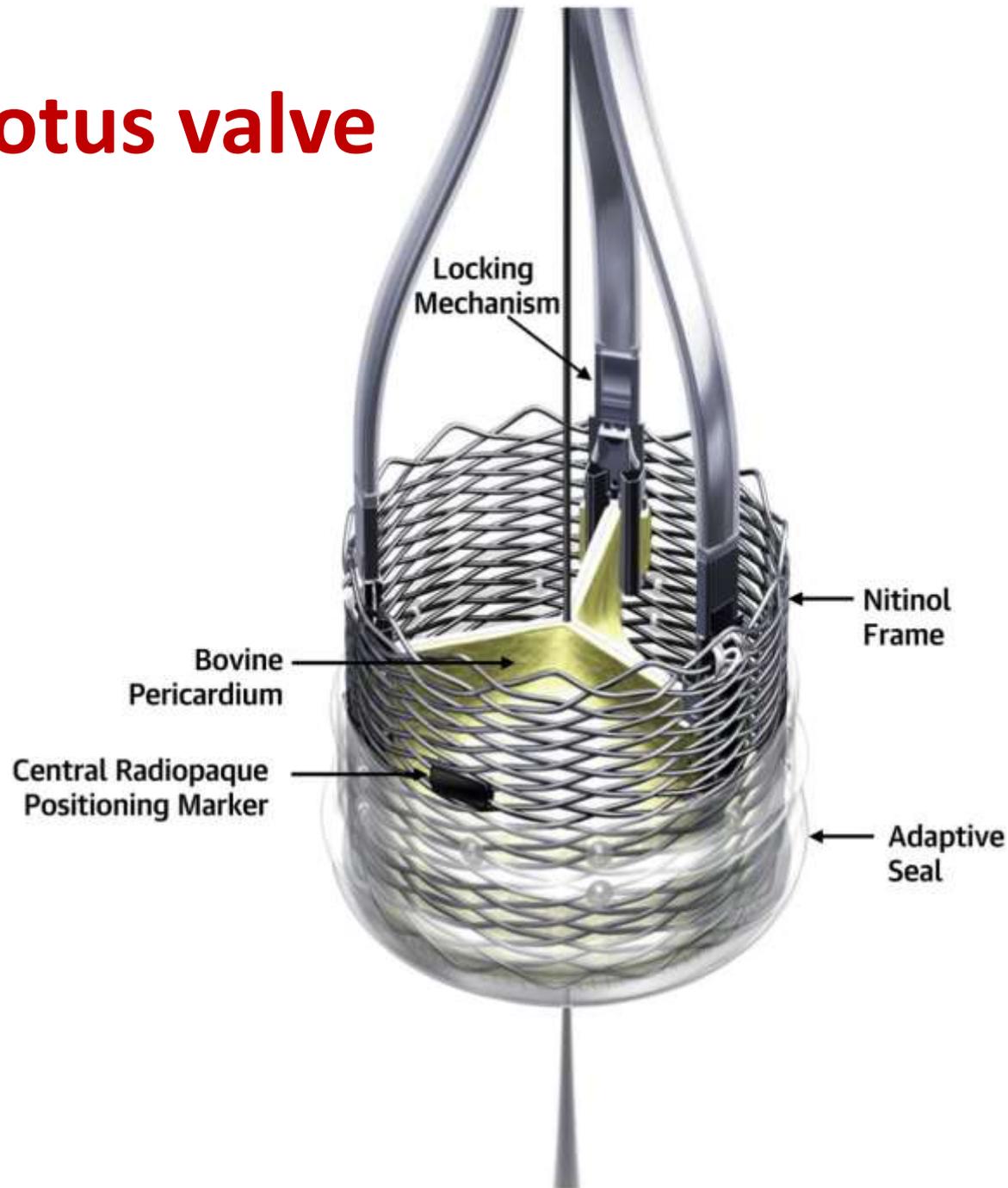
Transcatheter VIV for failed mitral bioprosthesis

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

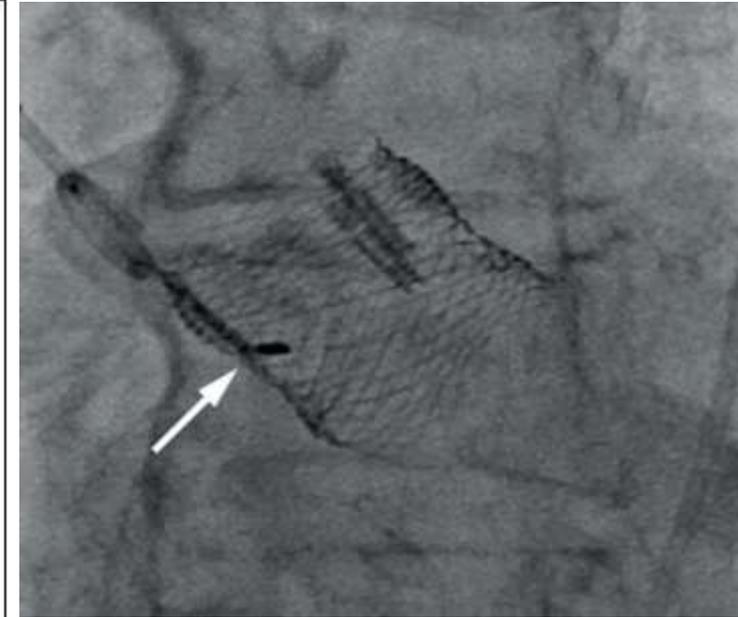
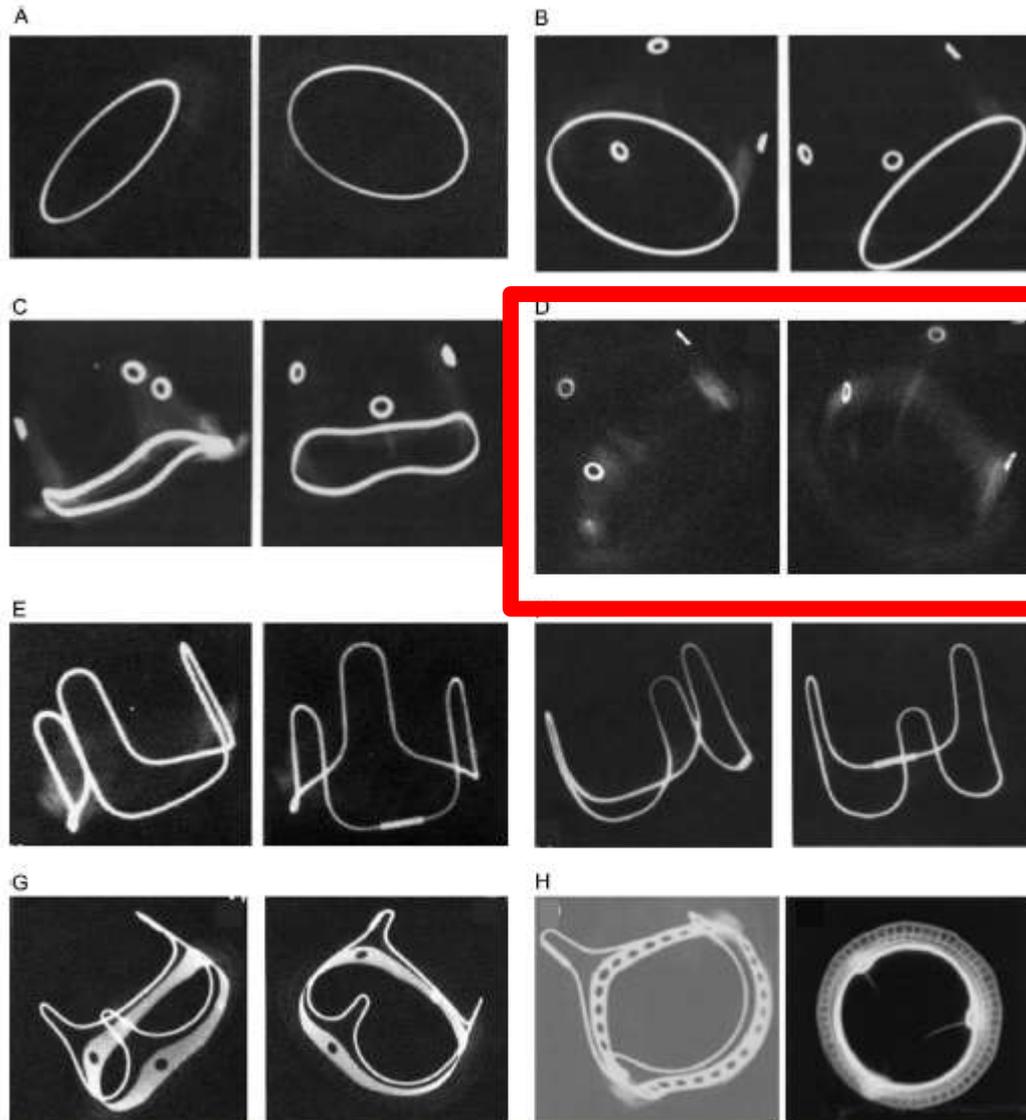


The beauty of Lotus valve

- **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.

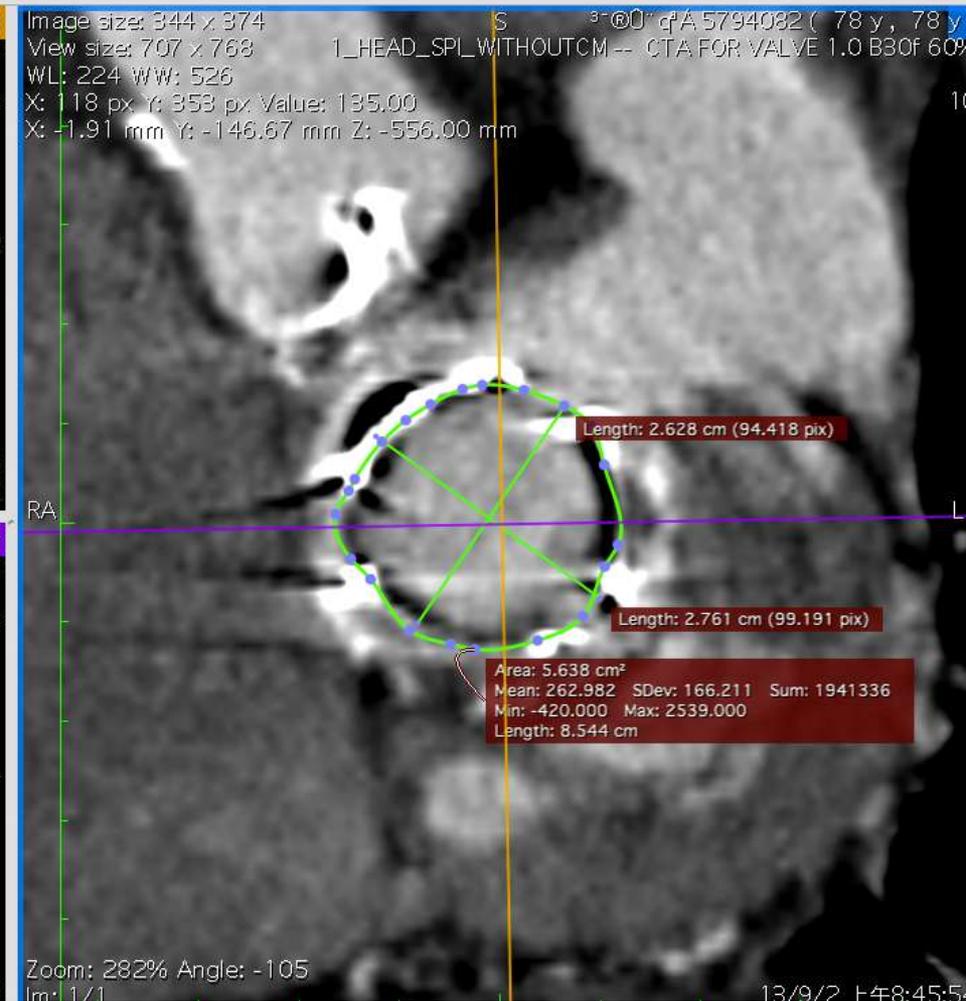
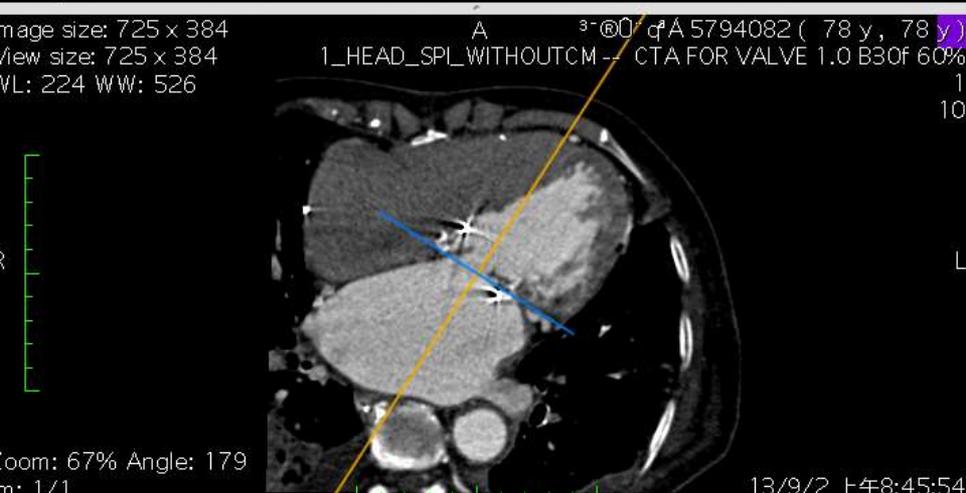
AV: Prosthetic: 8 mmHg MPG, 24 mmHg PPG.

MV: Prosthetic: 9 mmHg MPG, 20 mmHg PPG, MVA= 3.1 cm² by PHT.

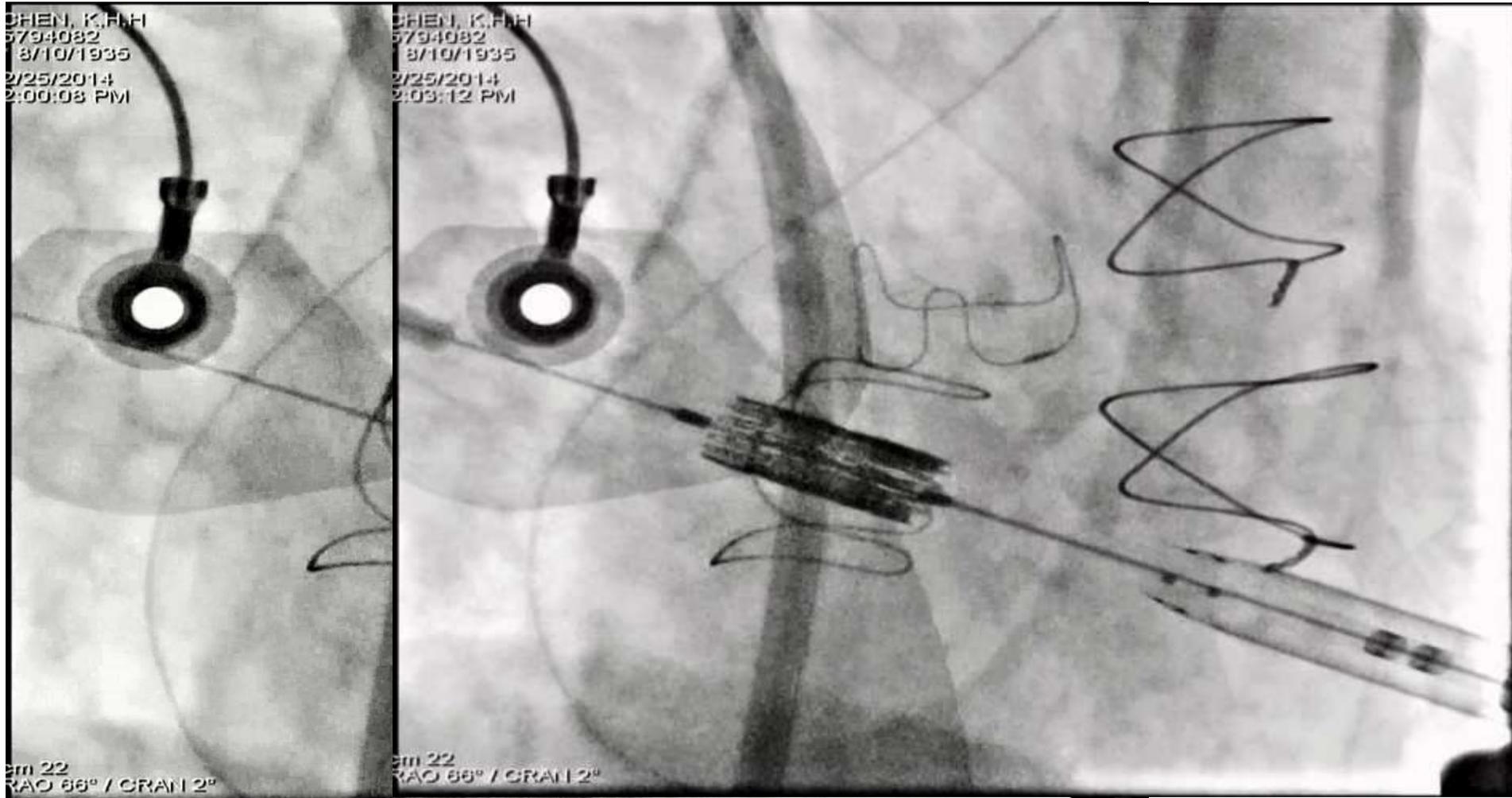
MR: Severe, TV: Repaired but with TR: Severe, RVSP= 42 mmHg. PR: Mild.

Inner diameter of mitral bioprosthesis

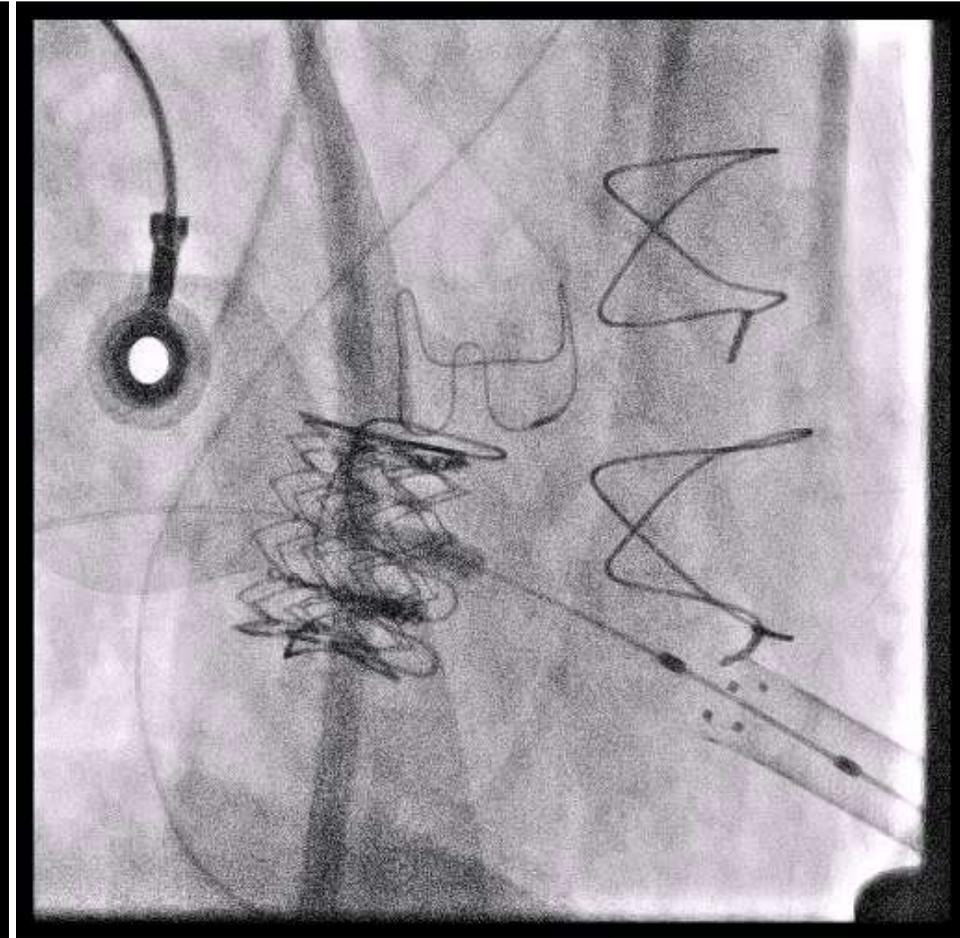
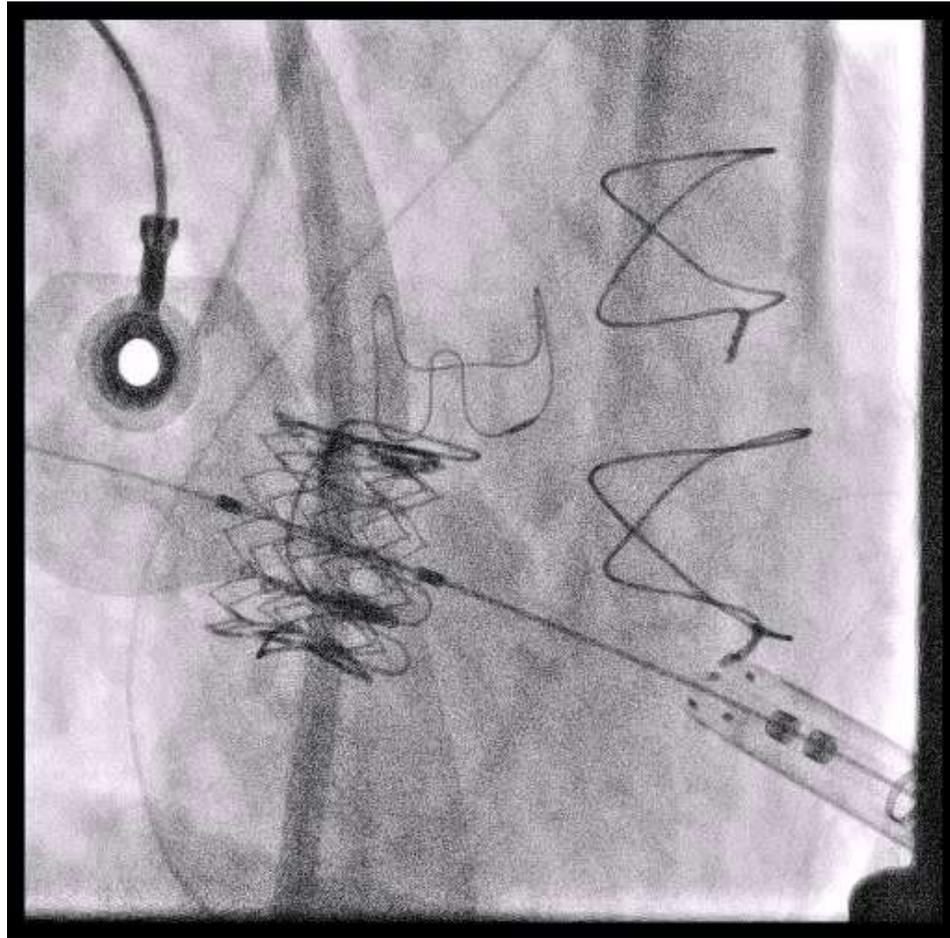
27mm



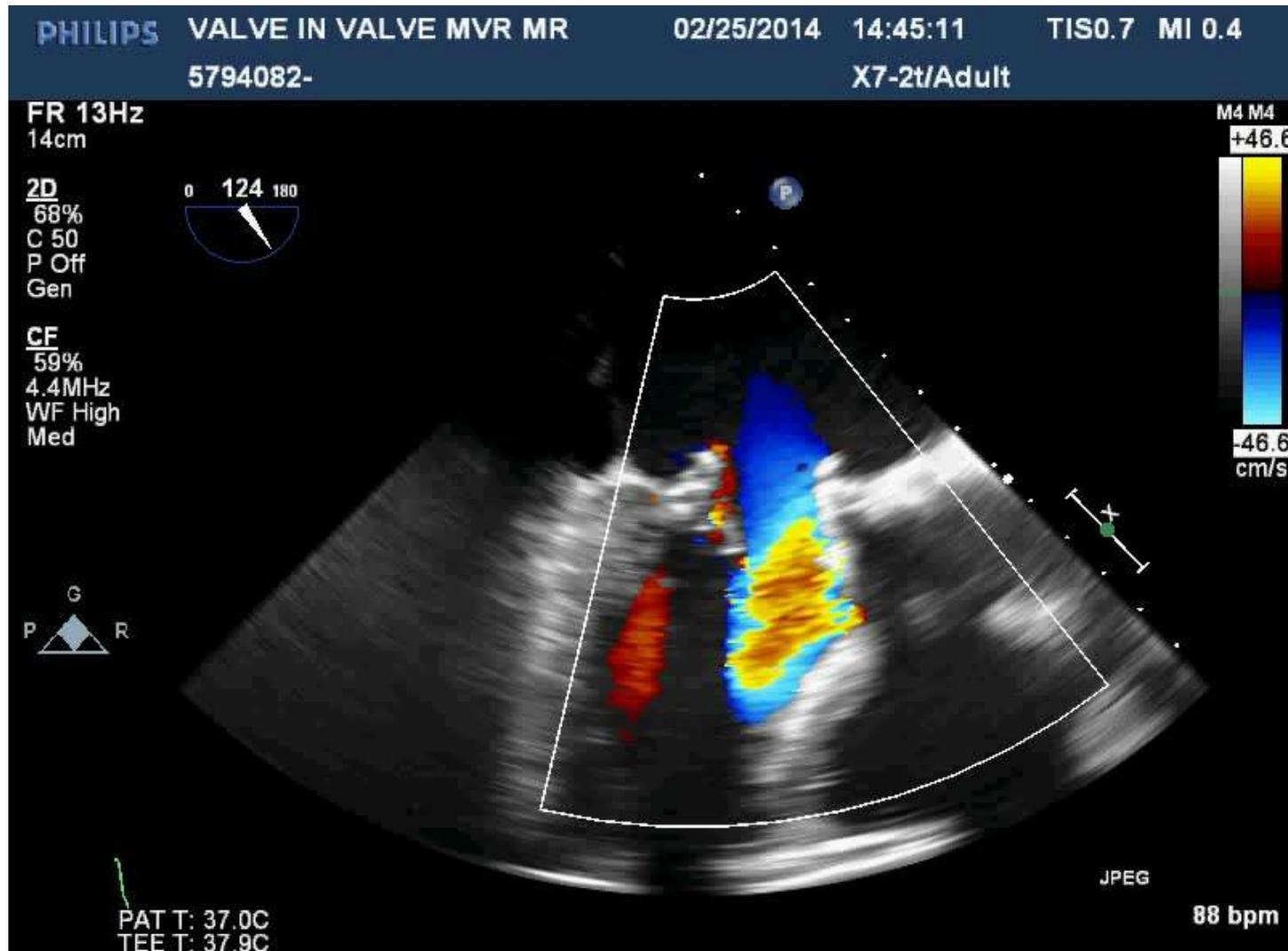
Transapical approach with an Ascendra 3 introducer and a 29mm Sapien XT



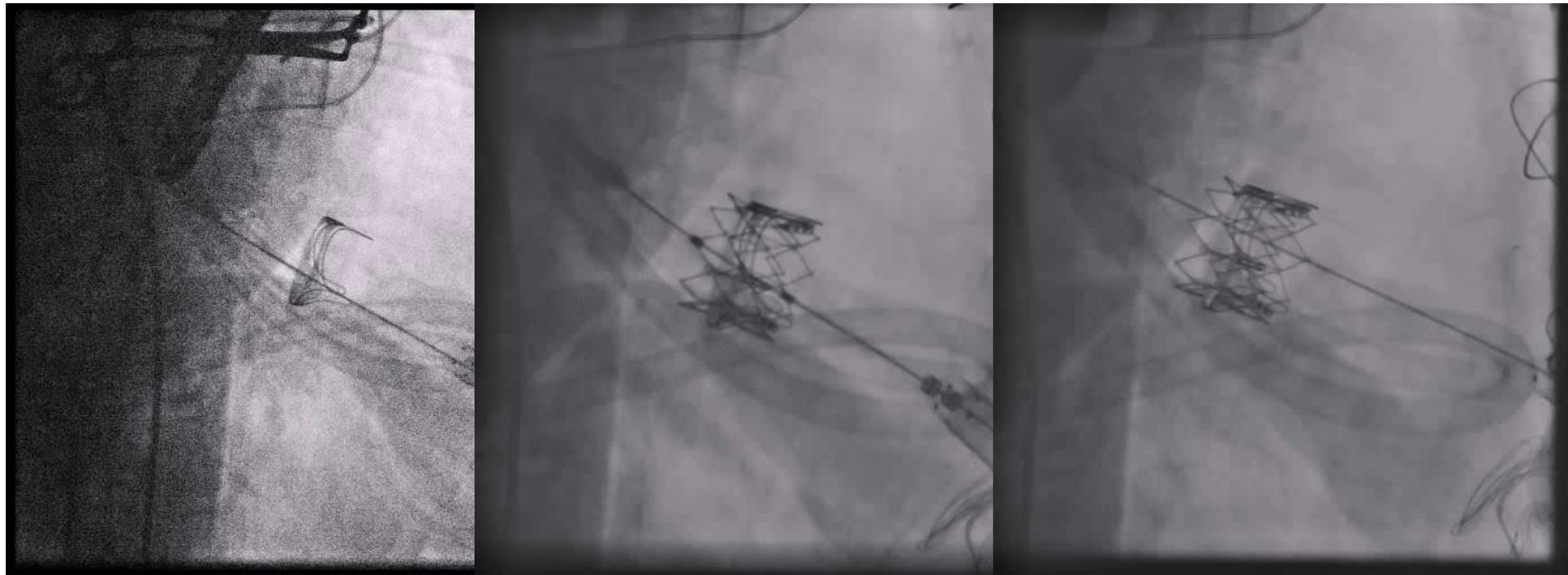
Transapical implantation of Sapien XT



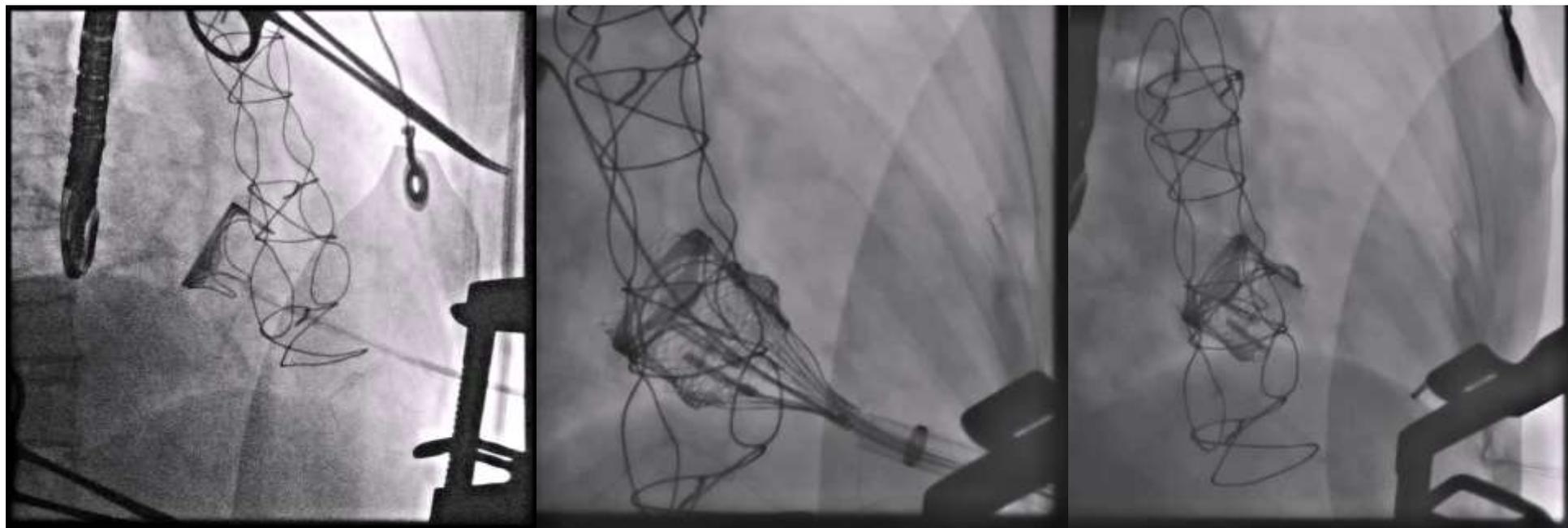
TEE after implantation of Sapien XT



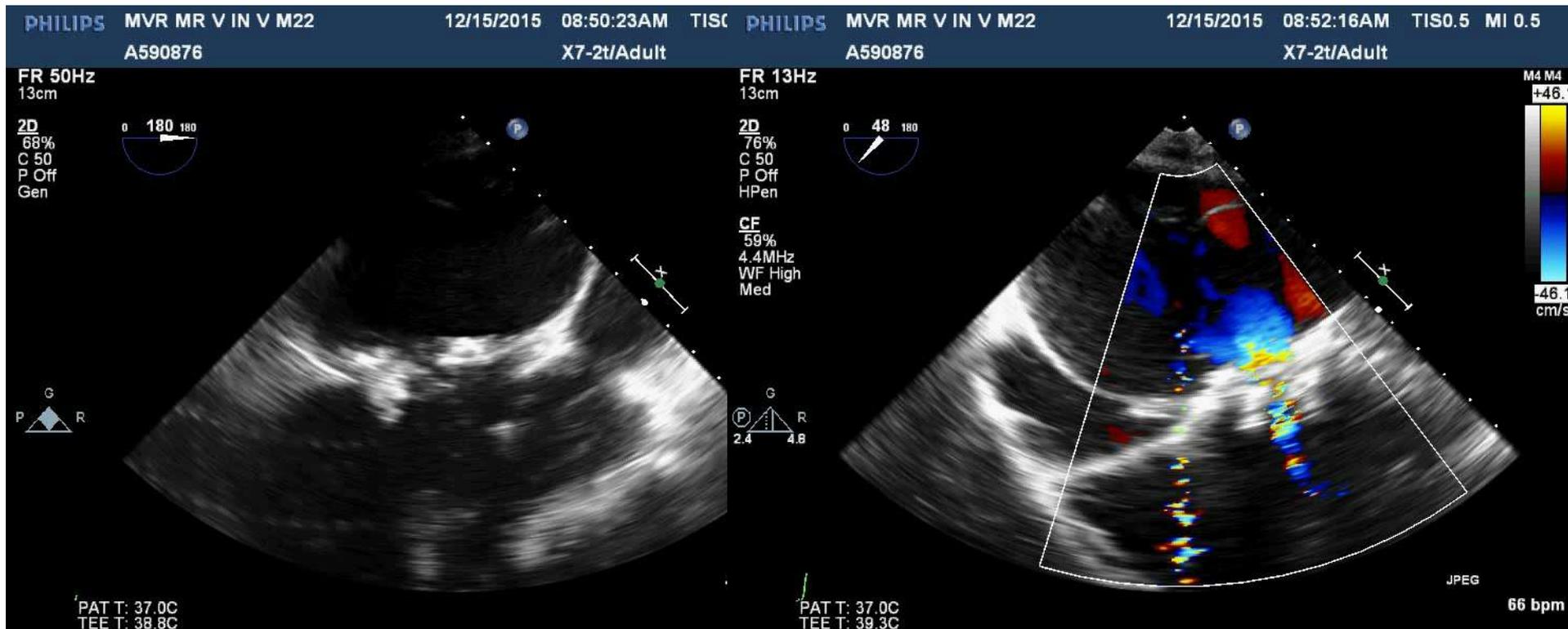
**M 82, presented with progressive dyspnea
for 4 months, Fc III-IV**



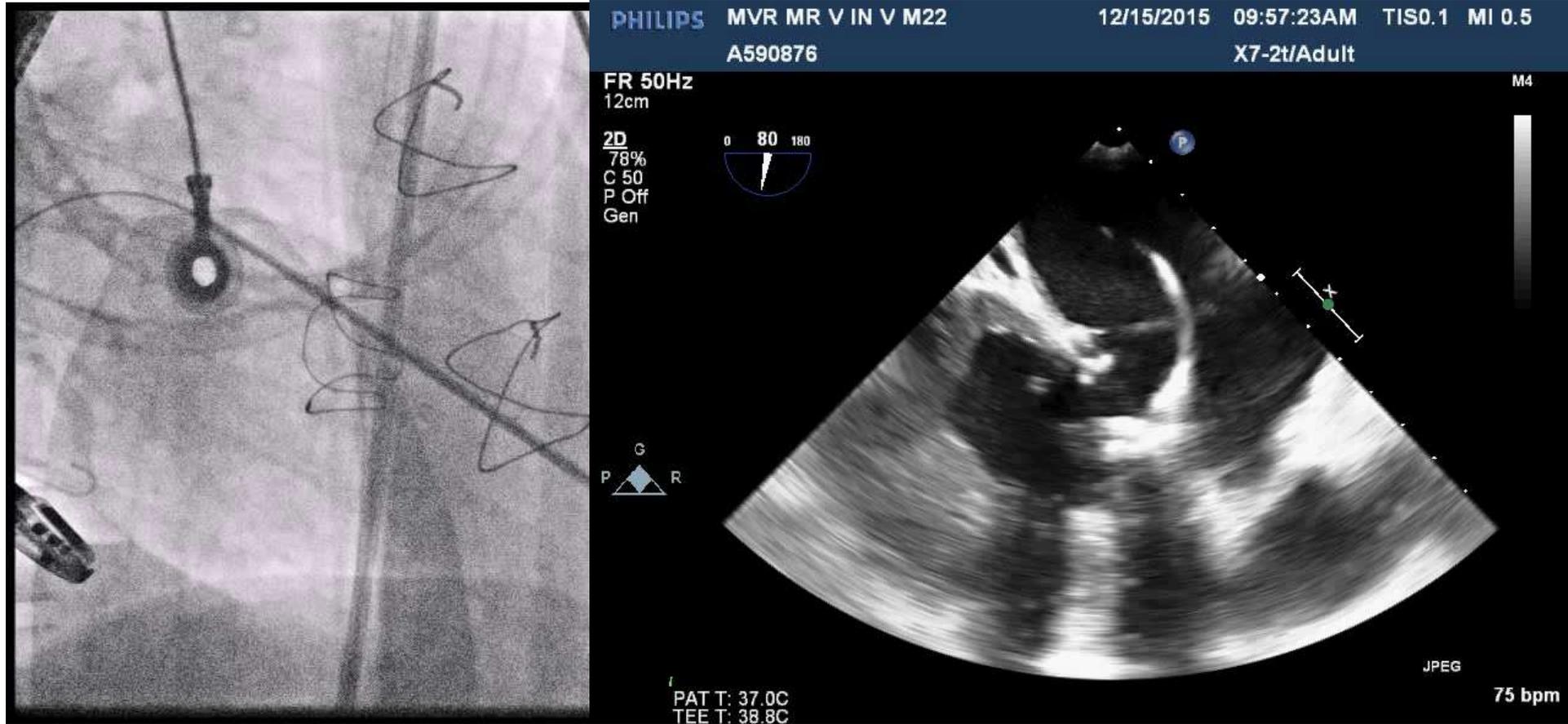
**M 82, presented with progressive dyspnea
for 4 months, Fc III-IV
Treated with Lotus system**



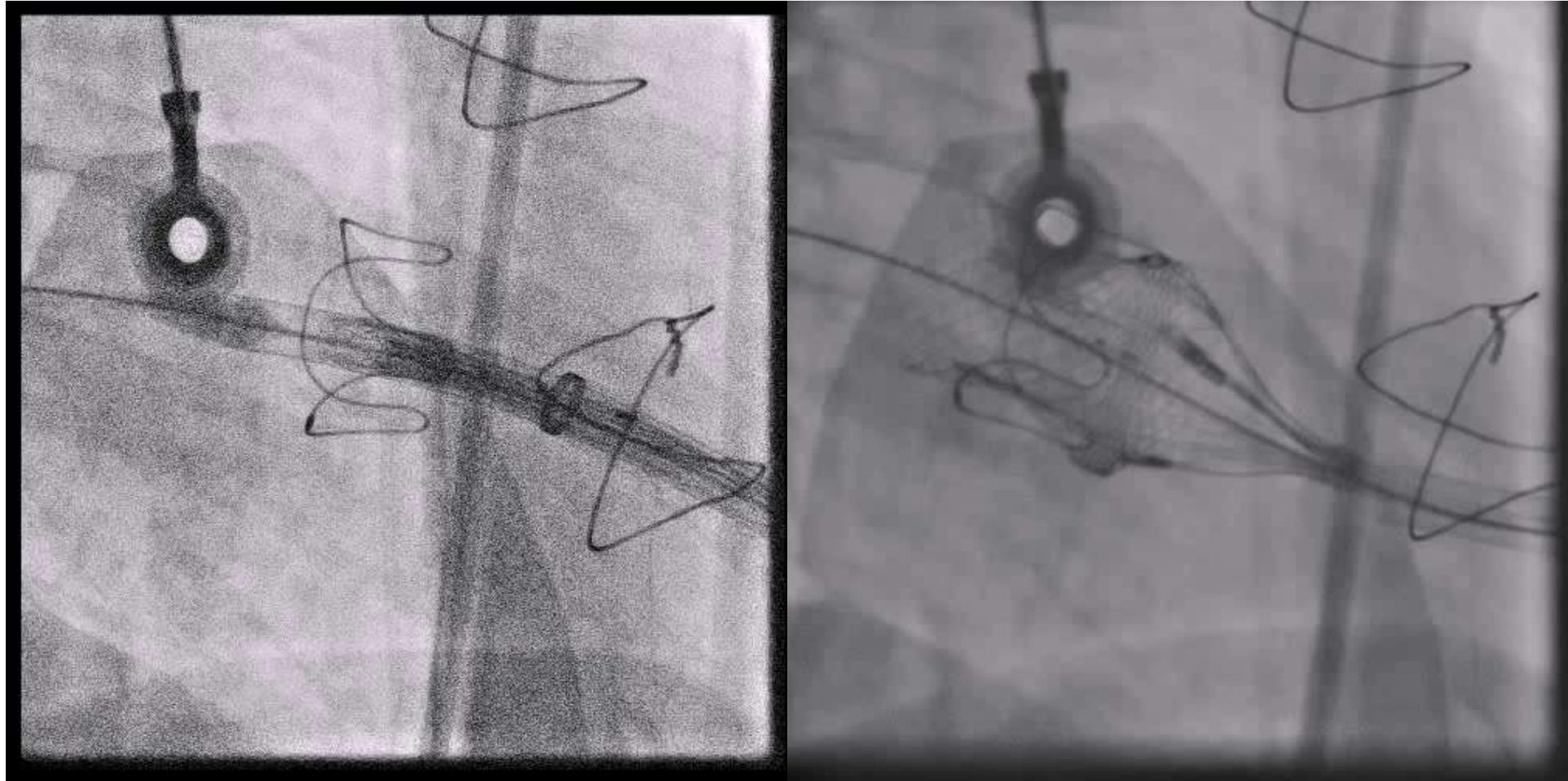
F 78, presented with progressive dyspnea for 3 months, Fc III-IV



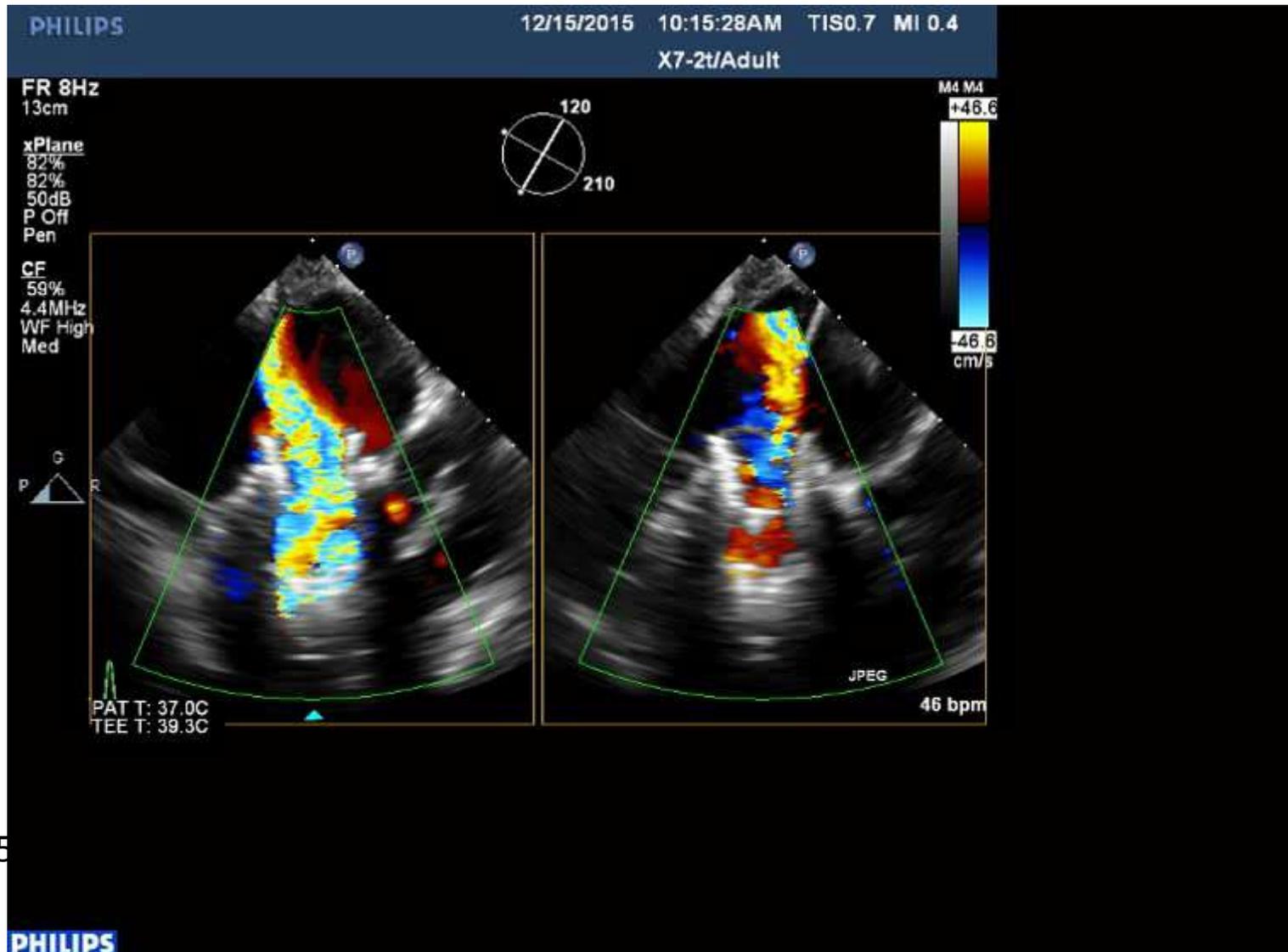
Wiring



Positioned a little high in LA

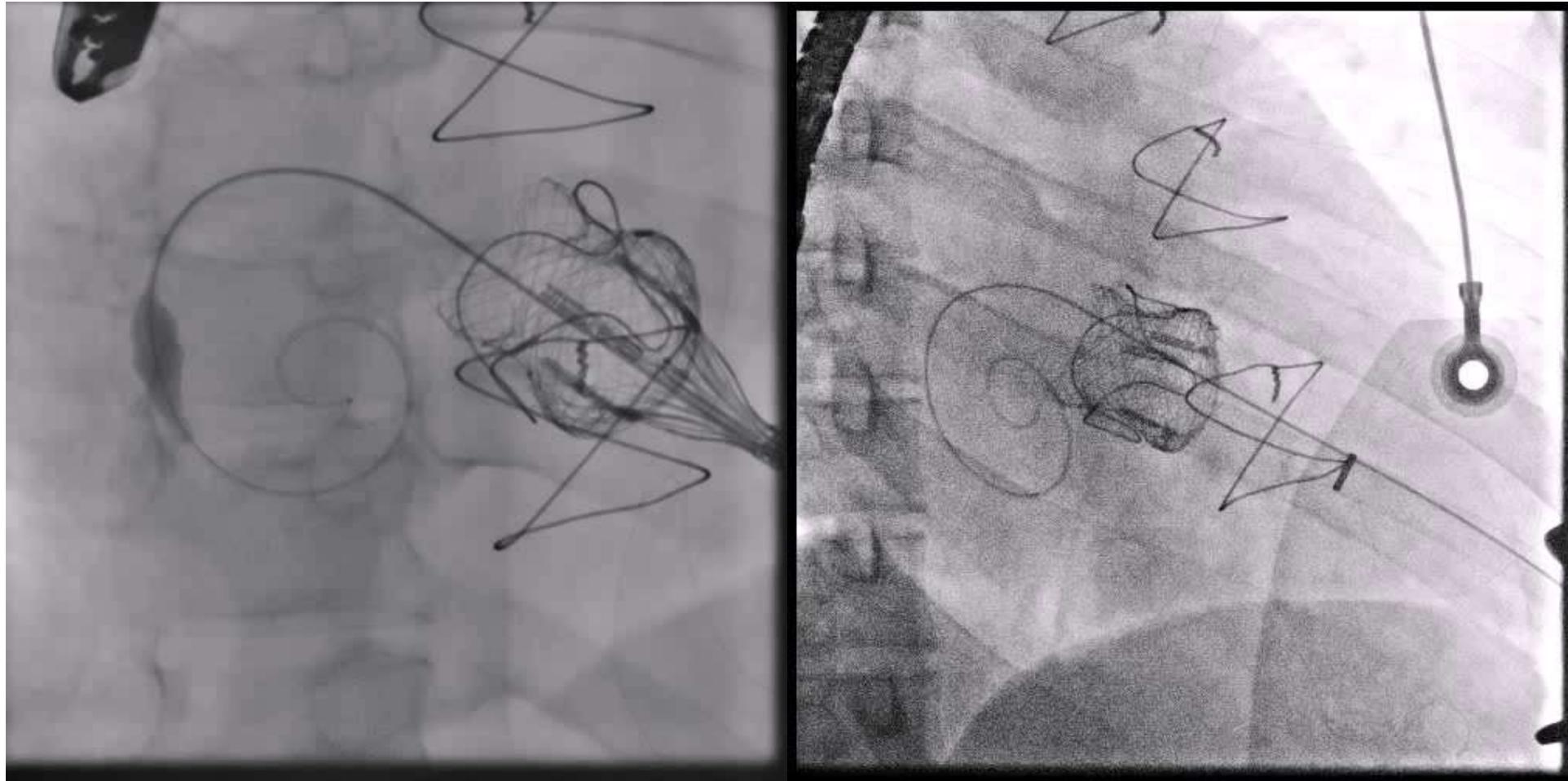


Positioned a little high in LA

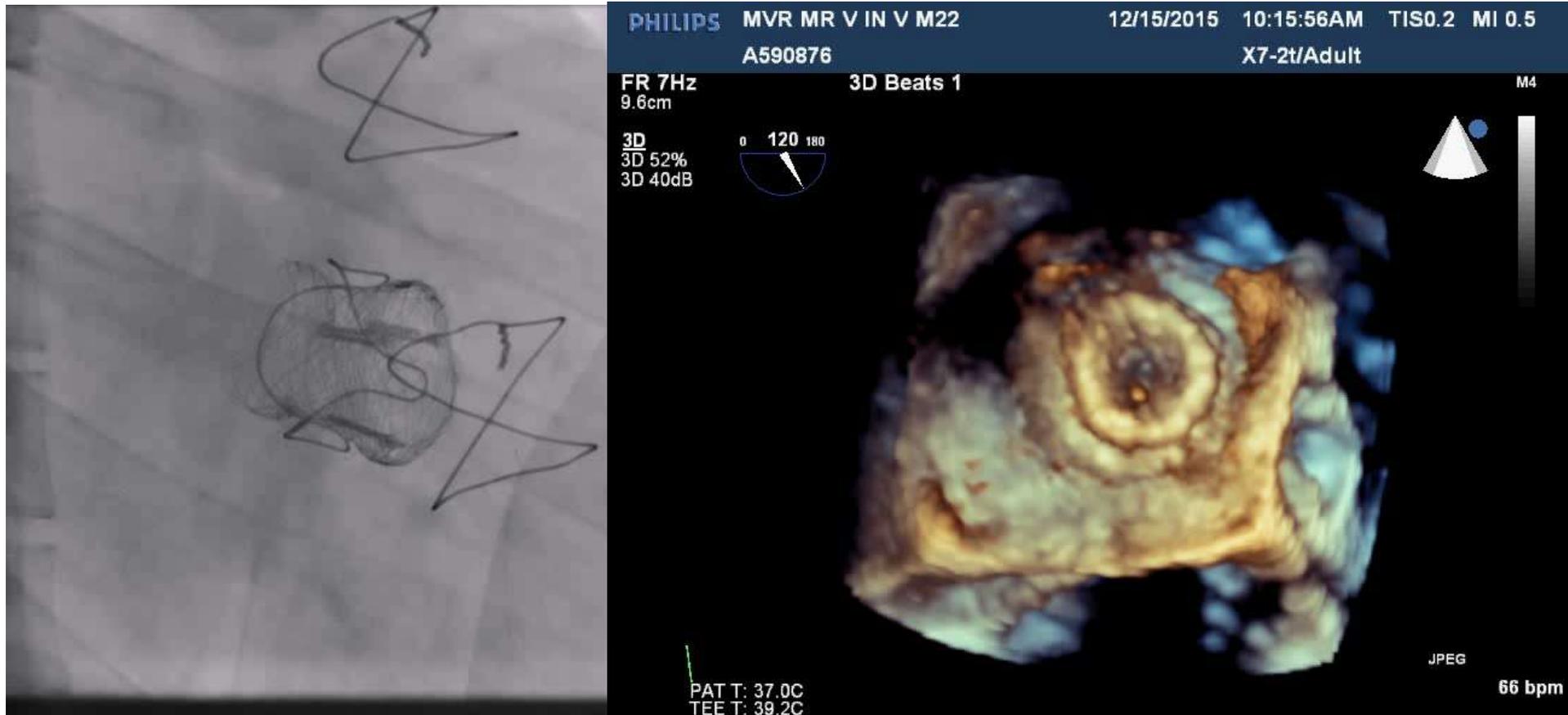


v in v_A5

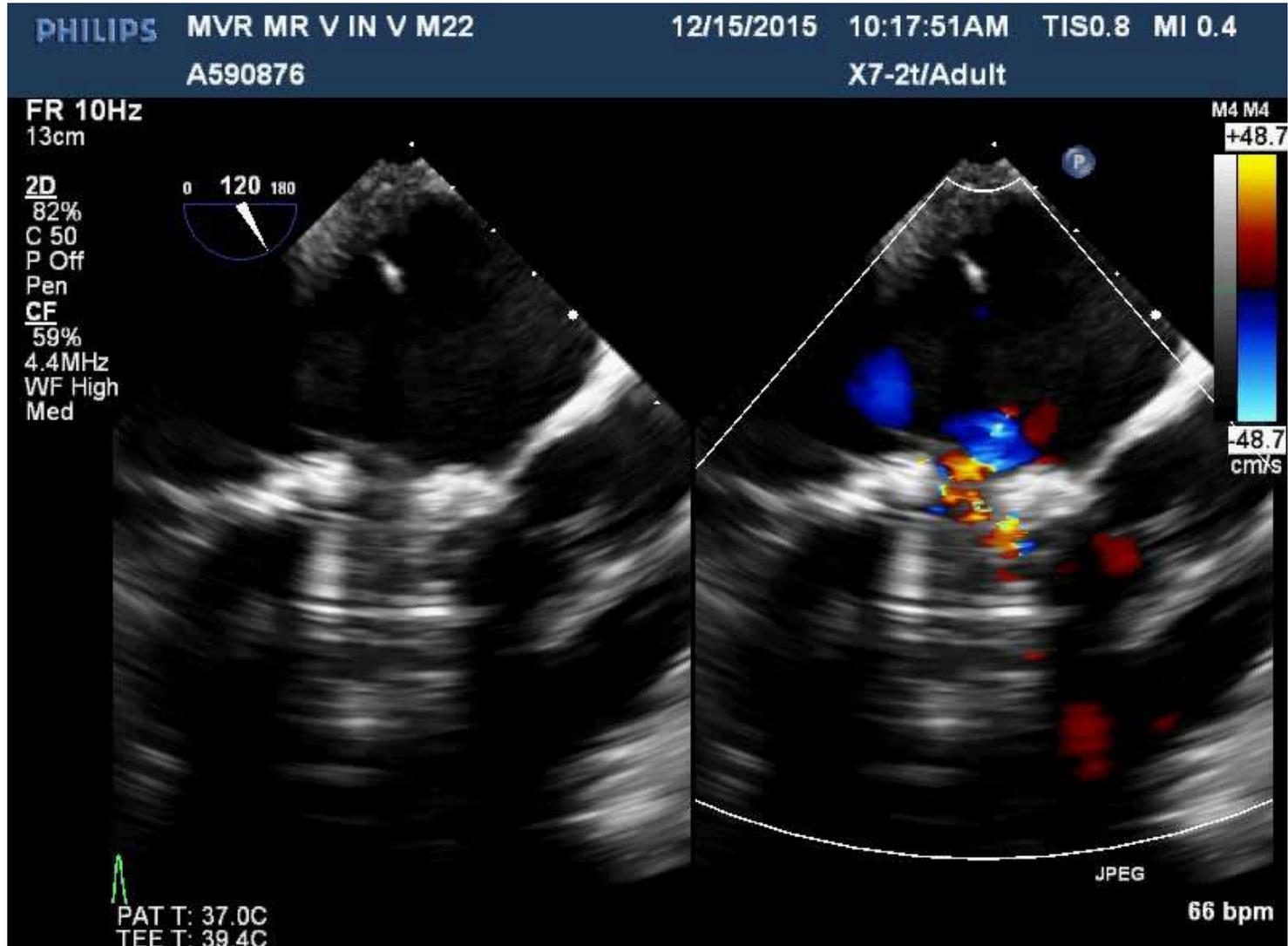
Re-sheathing and re-positioning



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.**