

What's next for structural heart programs: TAVR and beyond

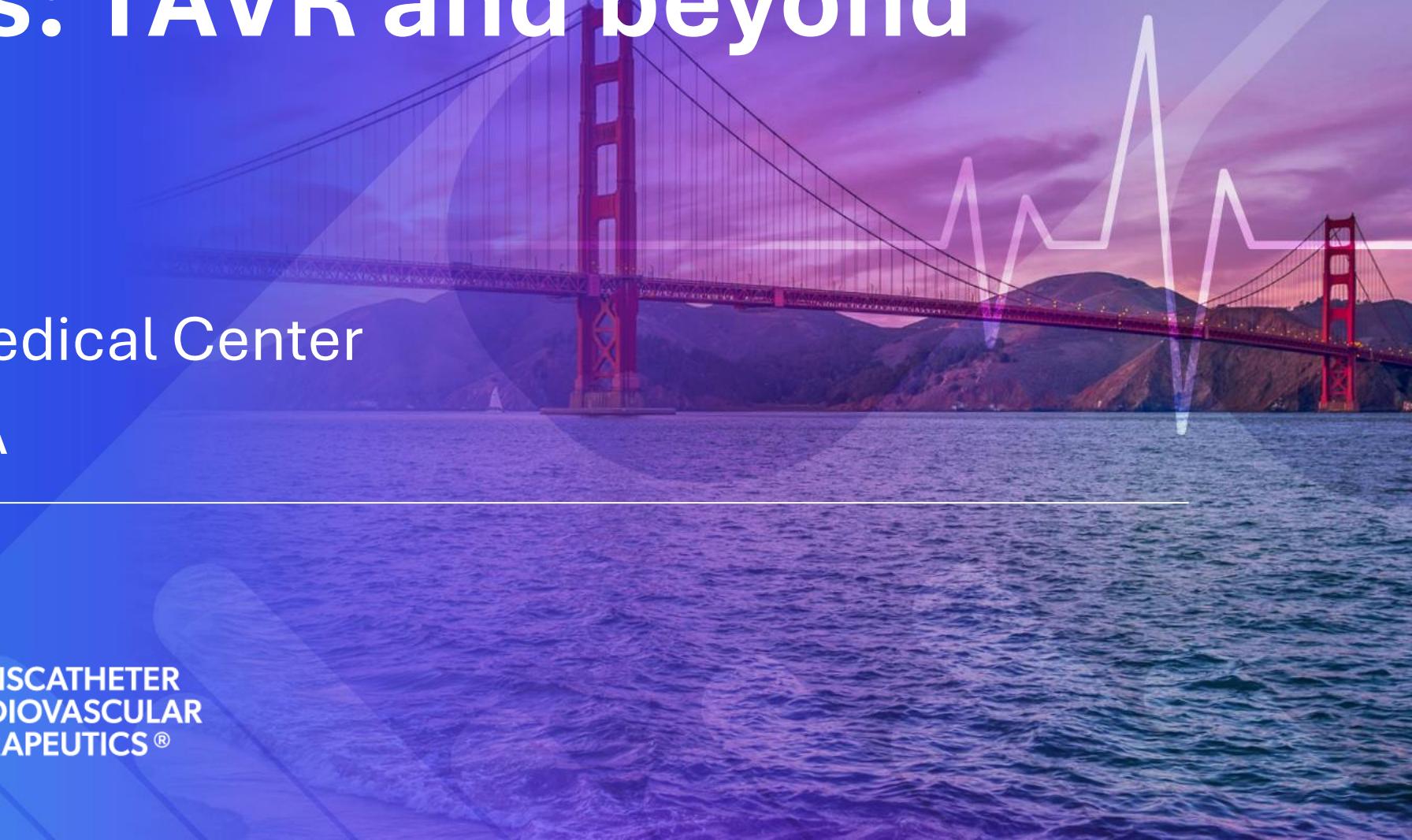
Raj Makkar, MD

Cedars-Sinai Medical Center

Los Angeles, CA



TRANSCATHETER
CARDIOVASCULAR
THERAPEUTICS®



Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship

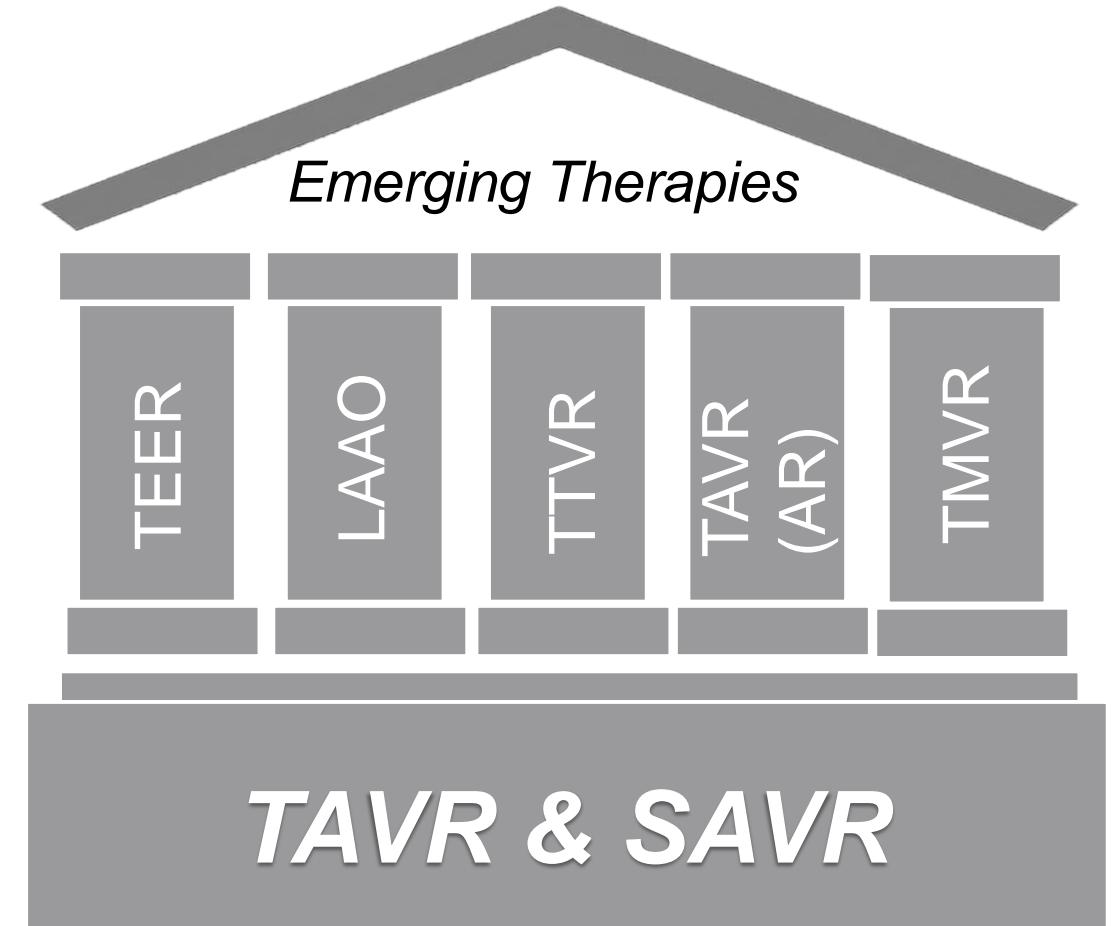
- Grant/Research Support
- Consultant Fees/Honoraria
- Individual Stock(s)/Stock Options
- Royalties/Patent Beneficiary
- Executive Role/Ownership Interest
- Other Financial Benefit

Ineligible Company

- [Edwards Lifesciences](#)
- [Company Name\(s\)](#)

TAVR is a Foundational Procedure for Providing Patients Transcatheter Valvular Therapies

- Establish protocols and infrastructure that translate directly to other valve therapies
- Positions program to leverage structural experience and expand into emerging therapies
- Attract patients and referrals to address increasing demand of structural heart procedures



Clinical Evidence is Informing TAVR Treatment Strategies

PROGRESSION OF AORTIC STENOSIS



Mild

Moderate

Severe
Asymptomatic

Severe
Symptomatic



THE
PROGRESS
TRIAL



THE
EARLY TAVR
TRIAL

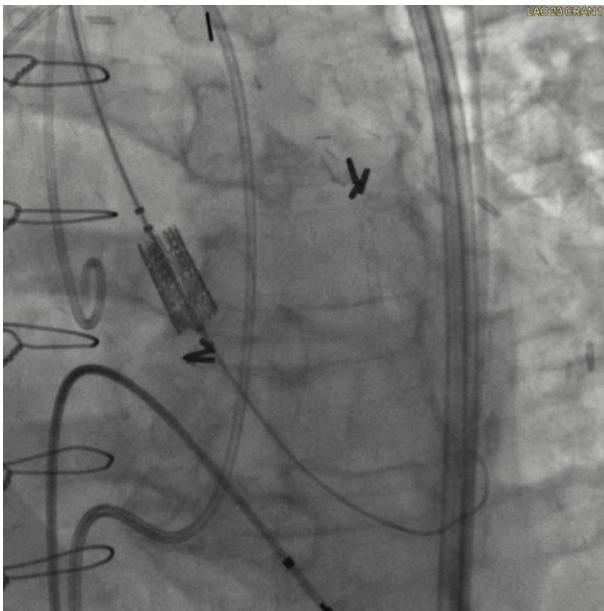


THE
PARTNER
TRIALS

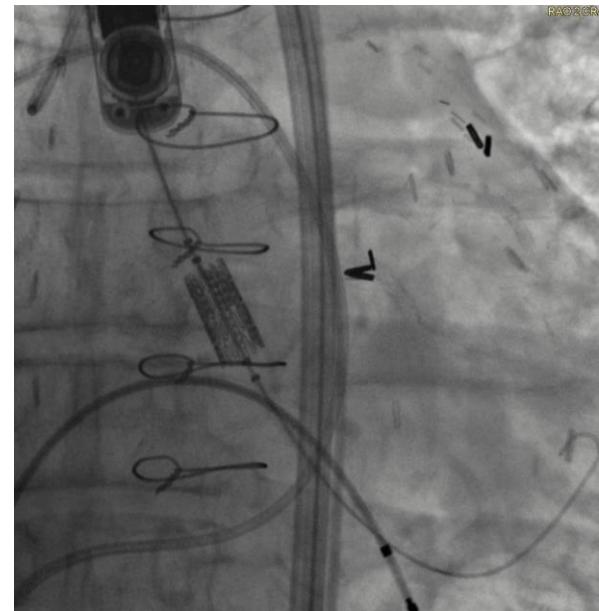
FIRST TAVR AT CEDARS-SINAI MEDICAL CENTER – November 26, 2007

Edwards-Sapien valve

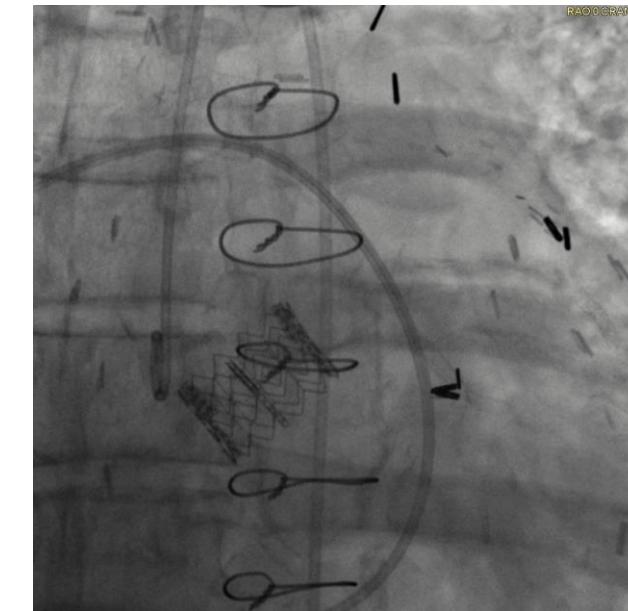
Positioning



Deployment



Final Result

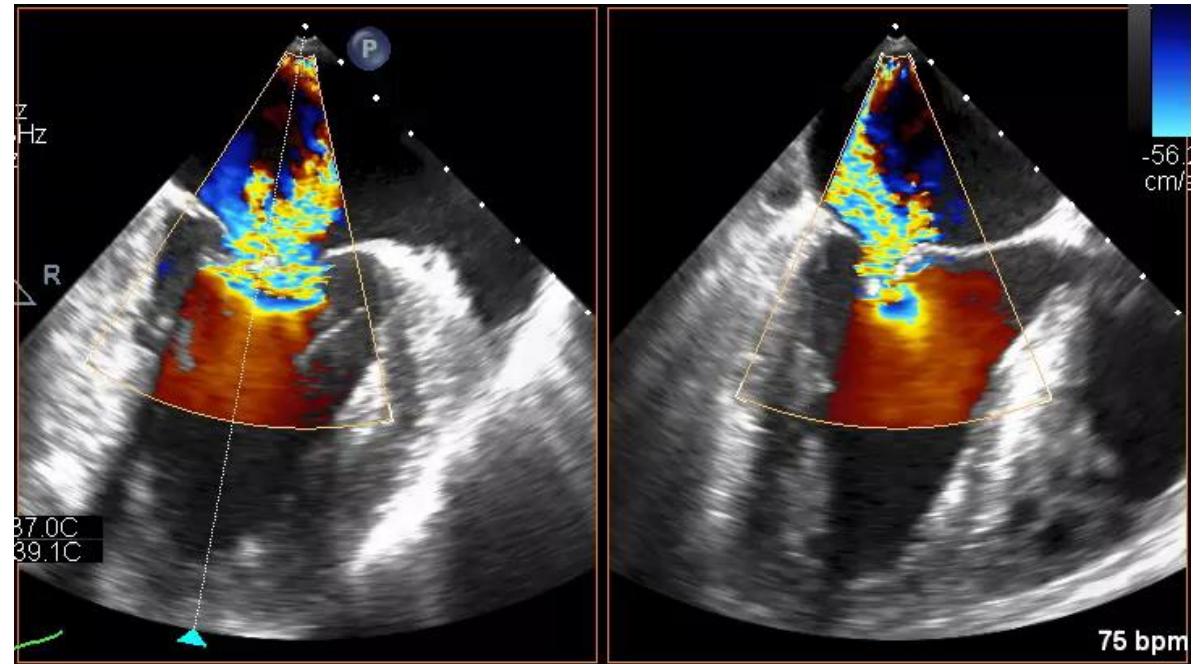


Clinical Presentation (January 2019)

59 y/o female presenting with shortness of breath, NYHA III heart failure due to severe functional MR

Past medical history

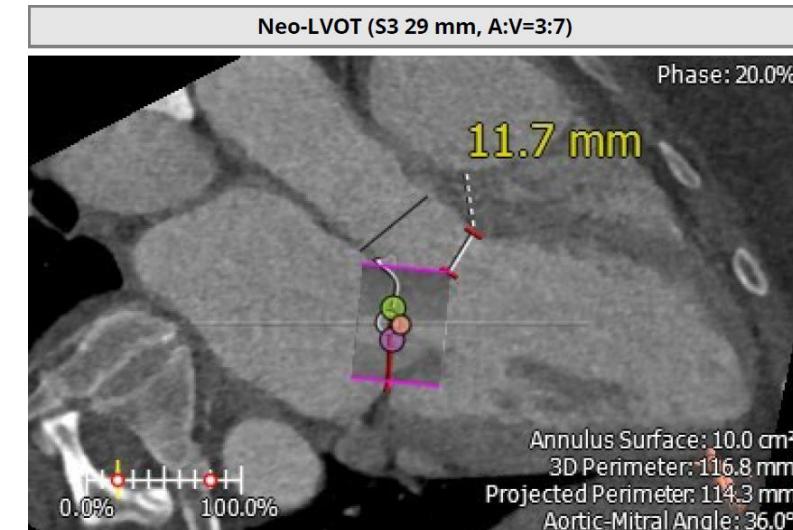
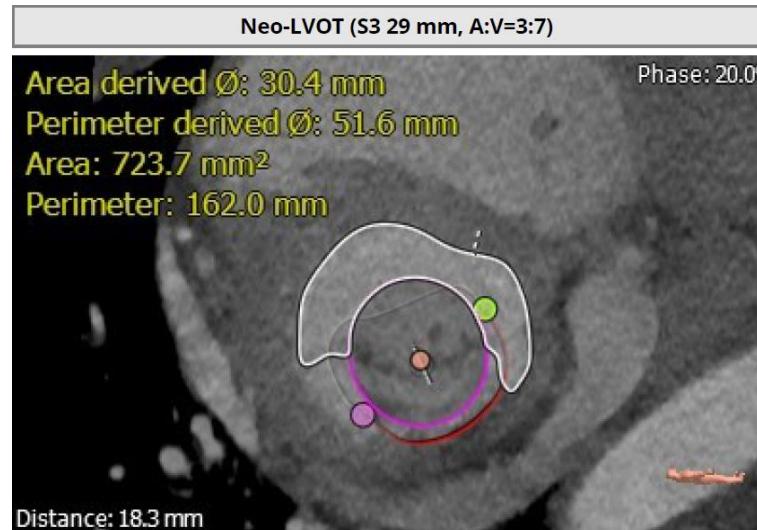
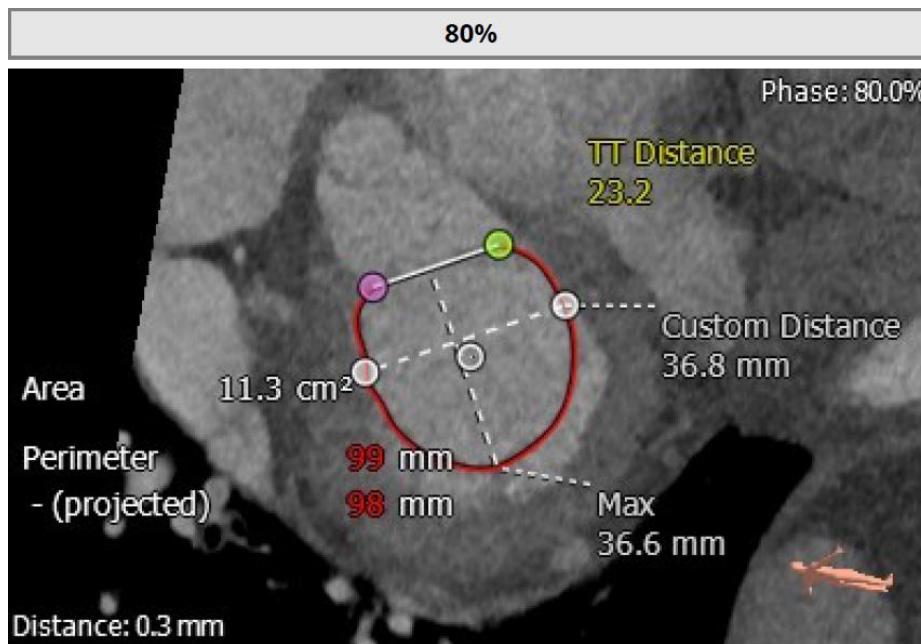
- Atrial fibrillation (on chronic AC)
- Type 2 Diabetes
- Hypertension
- Dyslipidemia
- CKD stage 3
- Morbid obesity (BMI 42 kg/m²)



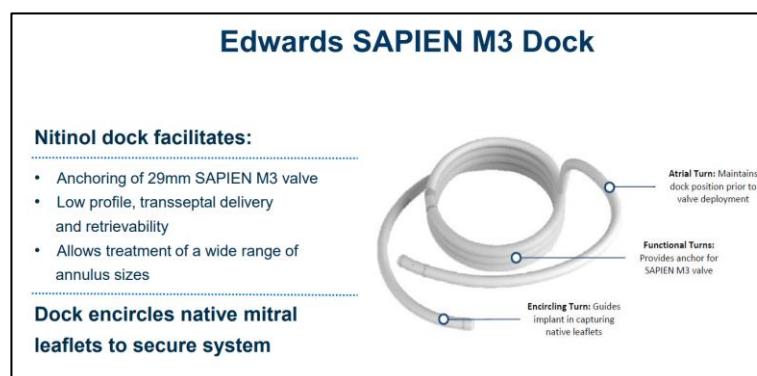
Severe Functional Mitral Regurgitation

CASE IMAGING

COMPUTED TOMOGRAPHY

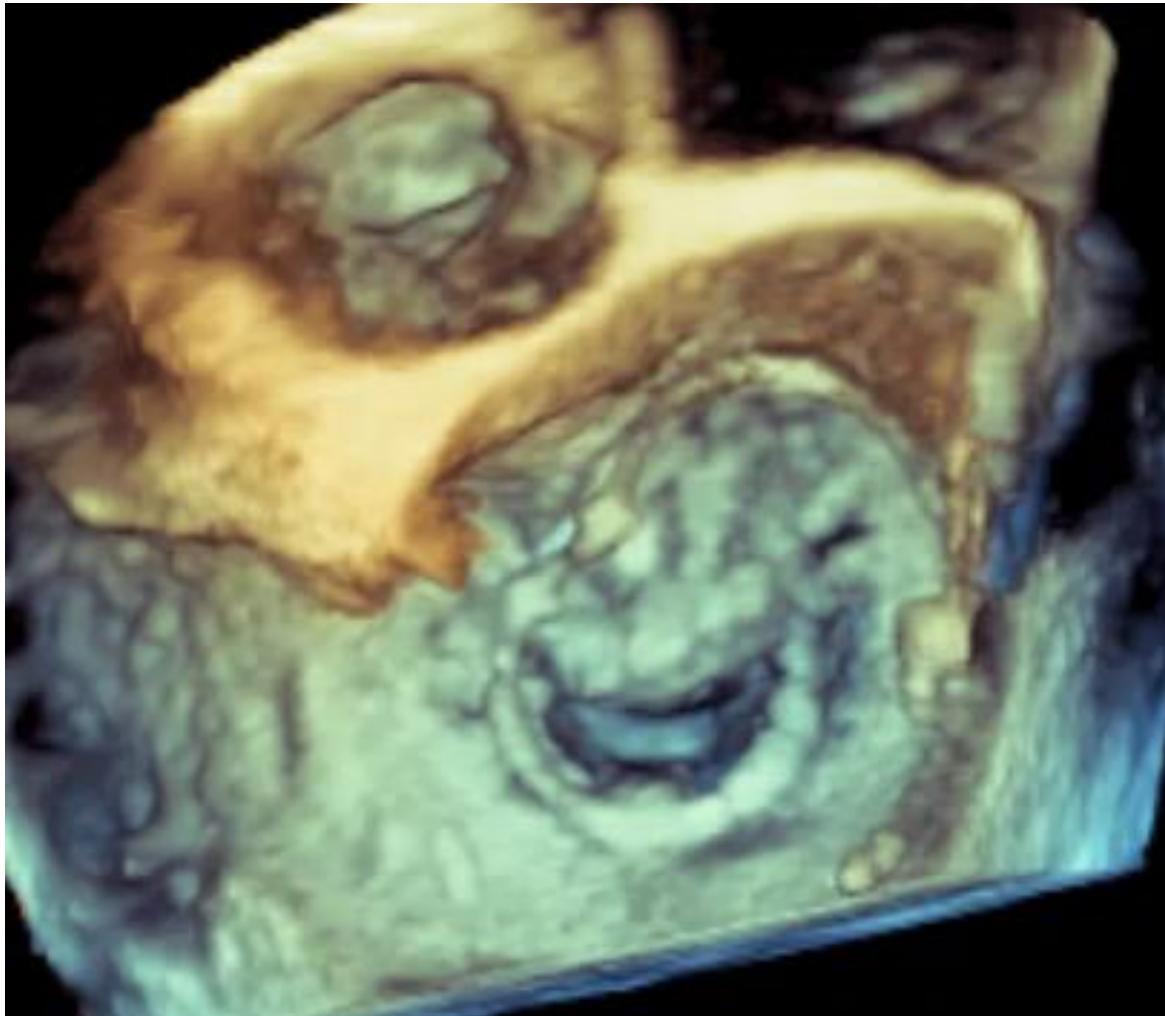


Annulus suitable for 29 mm Sapien M3
Low-risk of LVOT obstruction
Favorable aorto-mitral angle



Caution: Investigational device. Limited by United States law to investigation use.

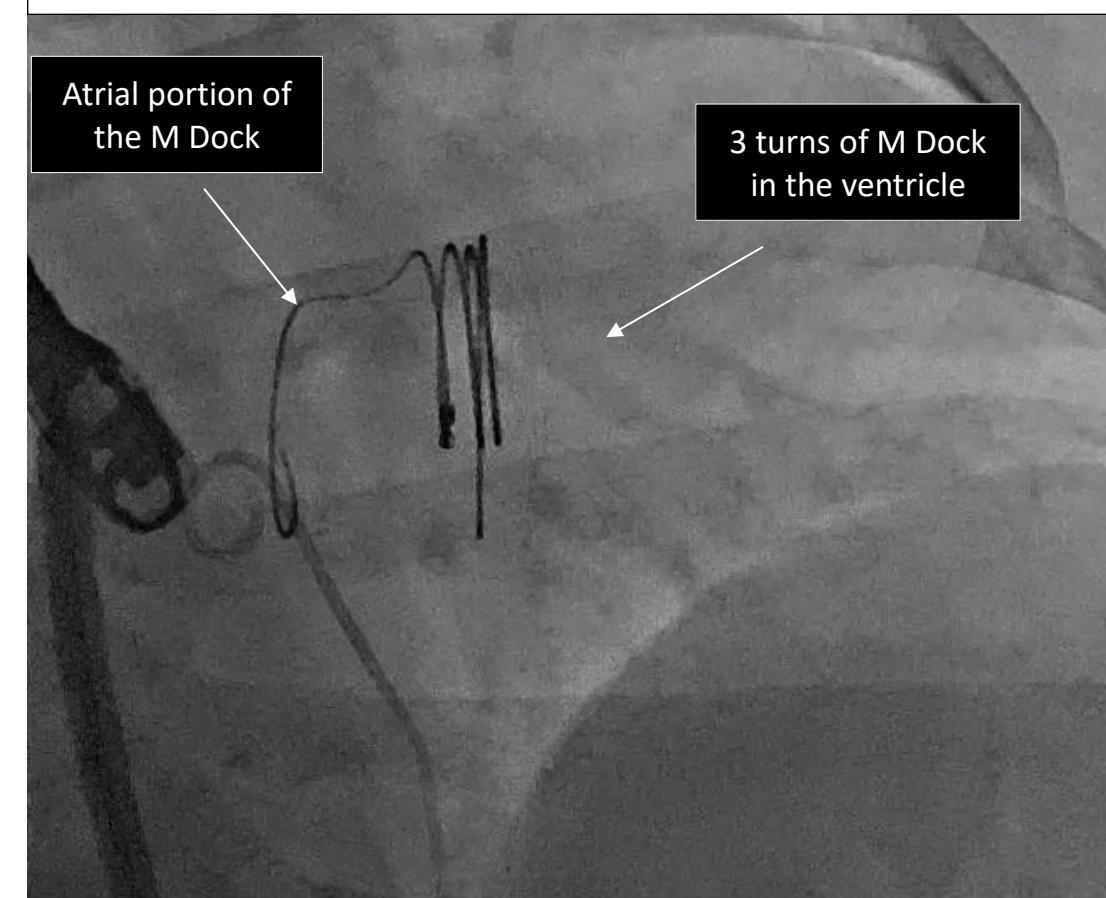
M Dock Release



Mdock released from the delivery system

Atrial portion of
the M Dock

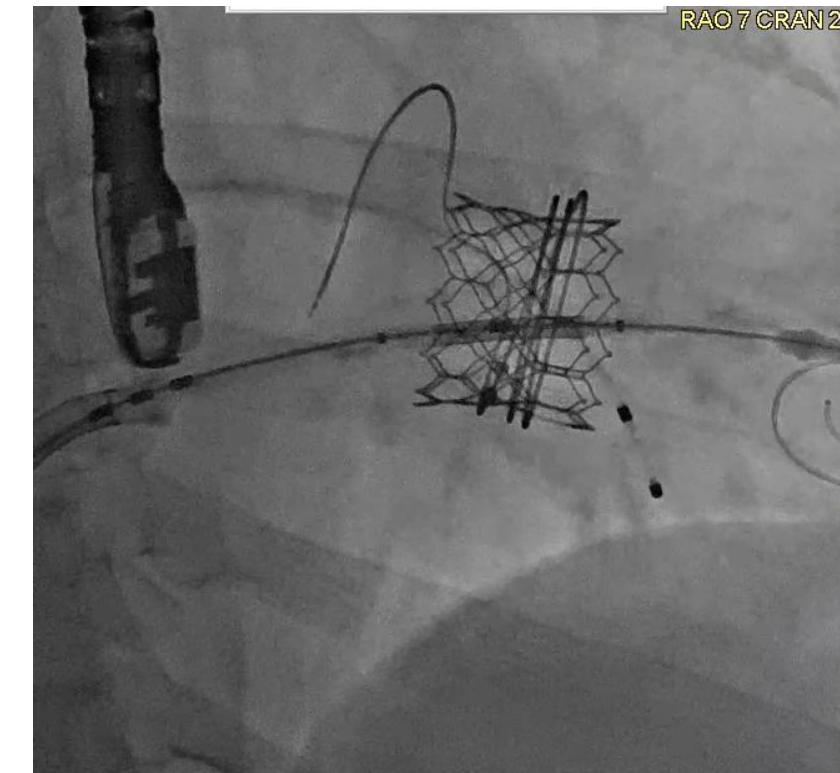
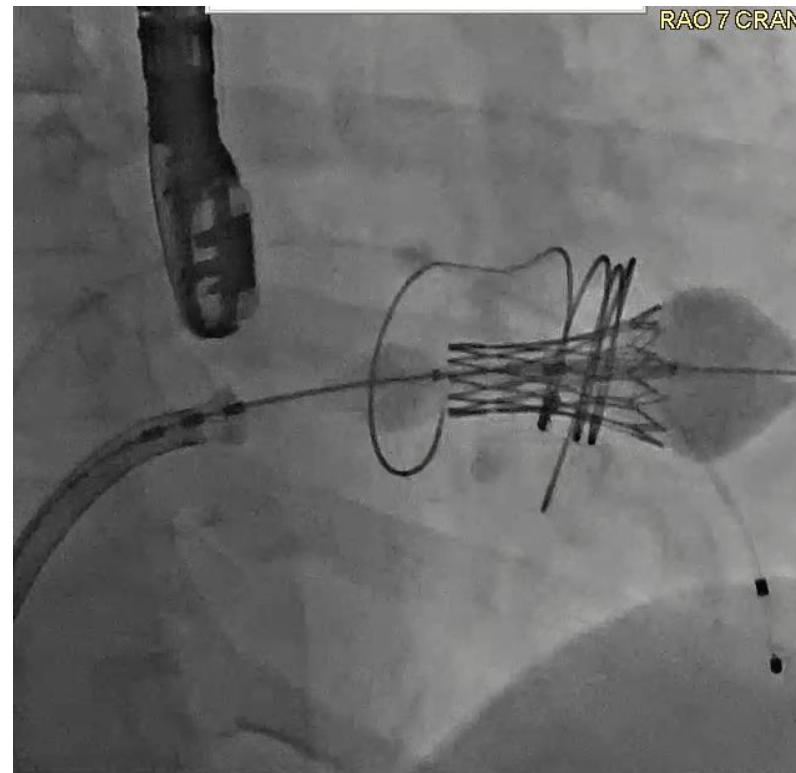
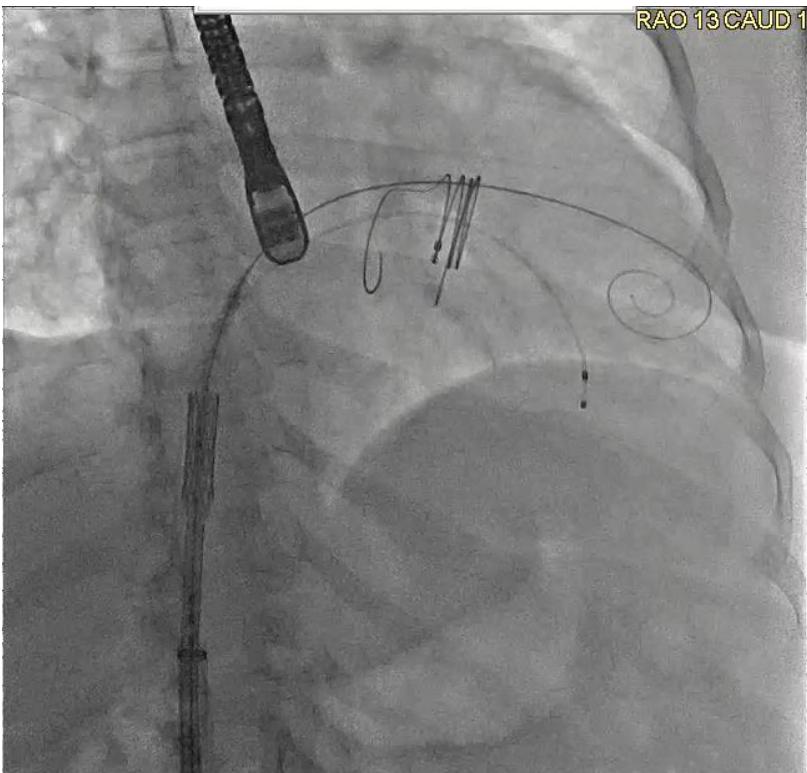
3 turns of M Dock
in the ventricle



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PROCEDURE

STEP 2: Deployment of Sapien M3 valve

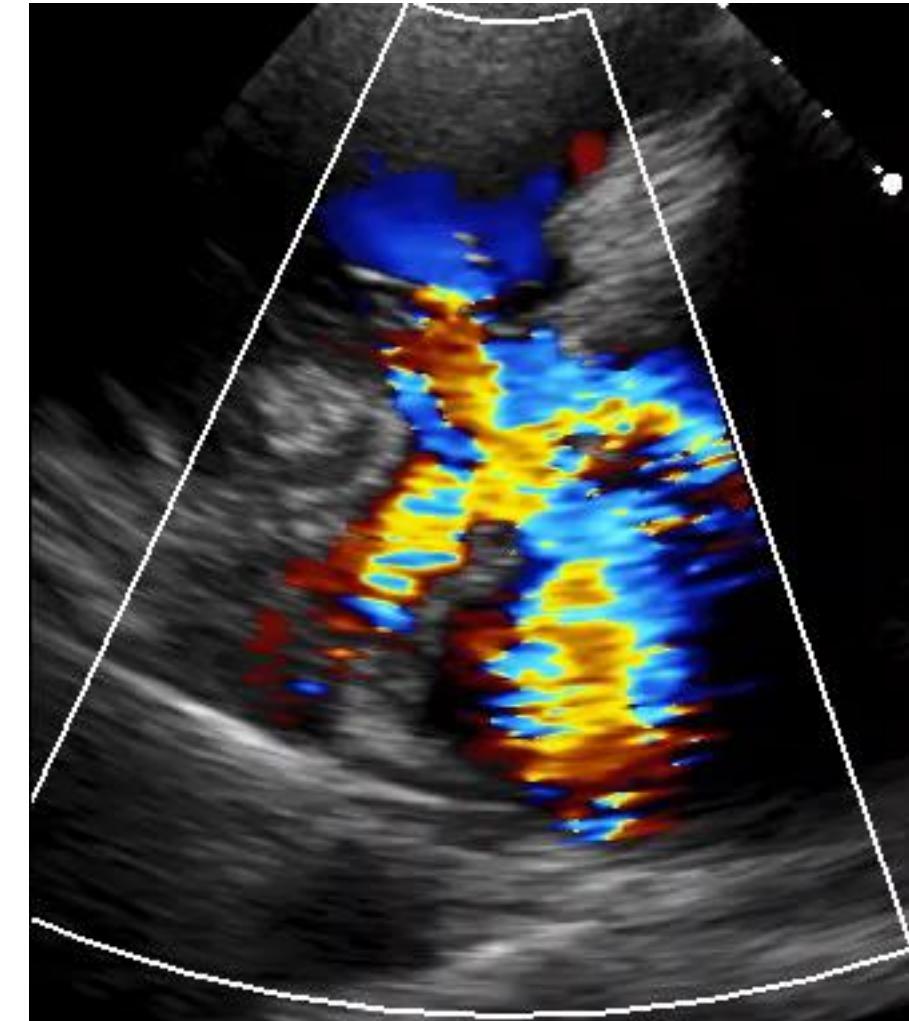
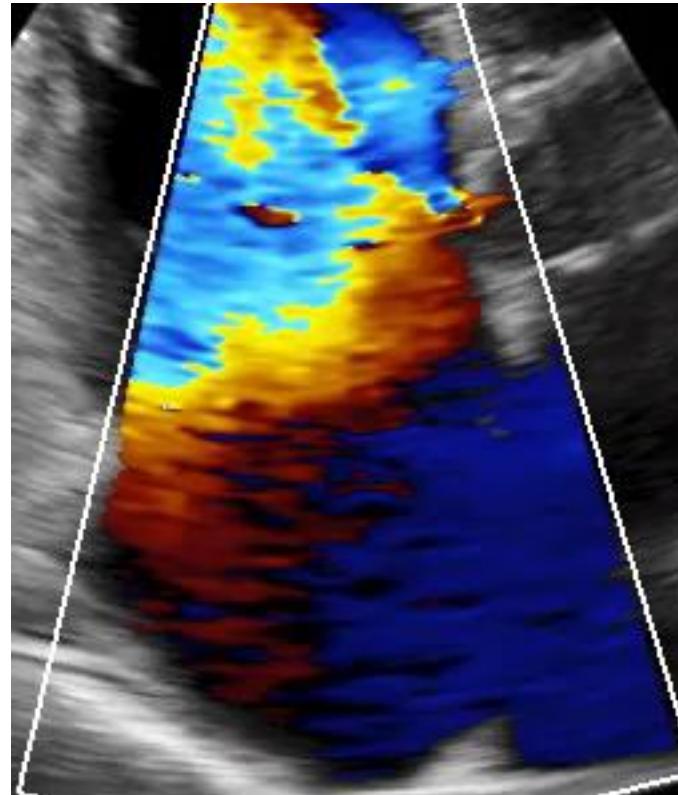
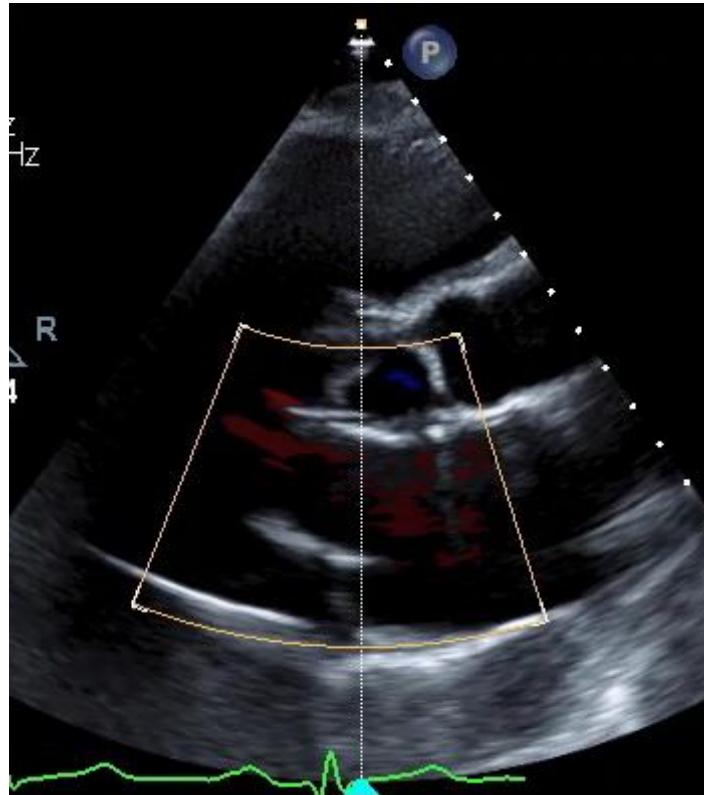


Sapien M3 deployment under rapid pacing

Post-dilatation with +4 cc

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1-YEAR FOLLOW-UP – NYHA Class III symptoms with severe dyspnea on exertion and Edema (June 2020)



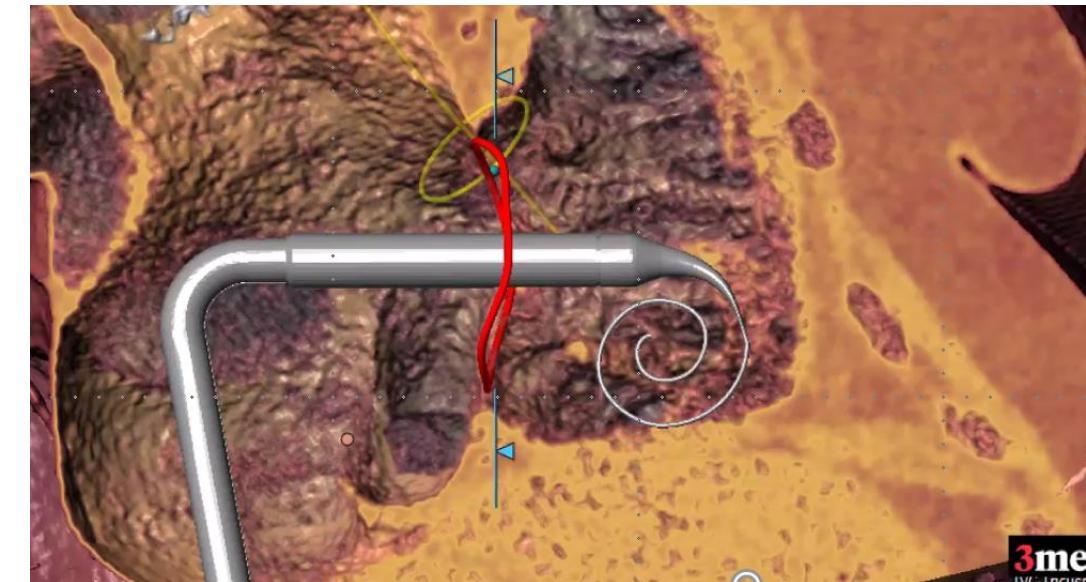
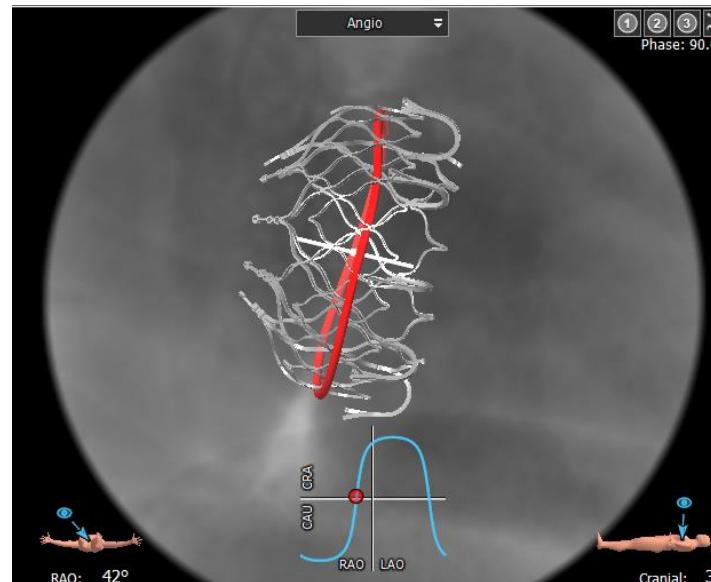
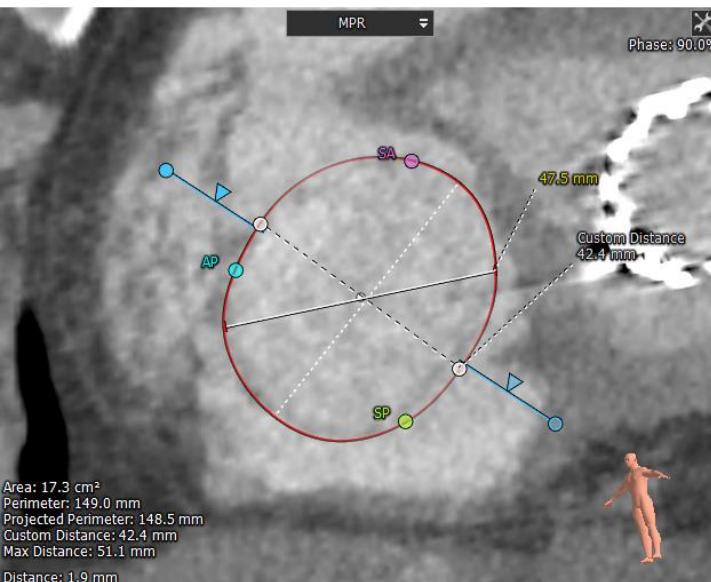
No central or mitral paravalvular leak

Severe TR (EROA: 0.62, TR Regurgitant Volume: 95 mL/beat)

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TRANSCATHETER TRICUSPID VALVE REPLACEMENT EVALUATION

COMPUTED TOMOGRAPHY



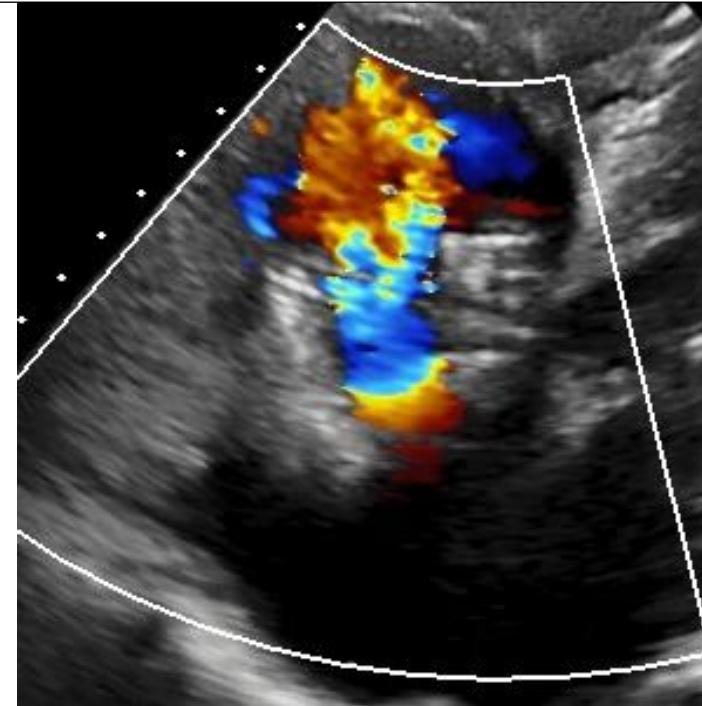
Annulus Perimeter: 149 mm
Favorable for 48mm Edwards Evoque valve
Favorable delivery system trajectory
IVC to the Tricuspid Annulus



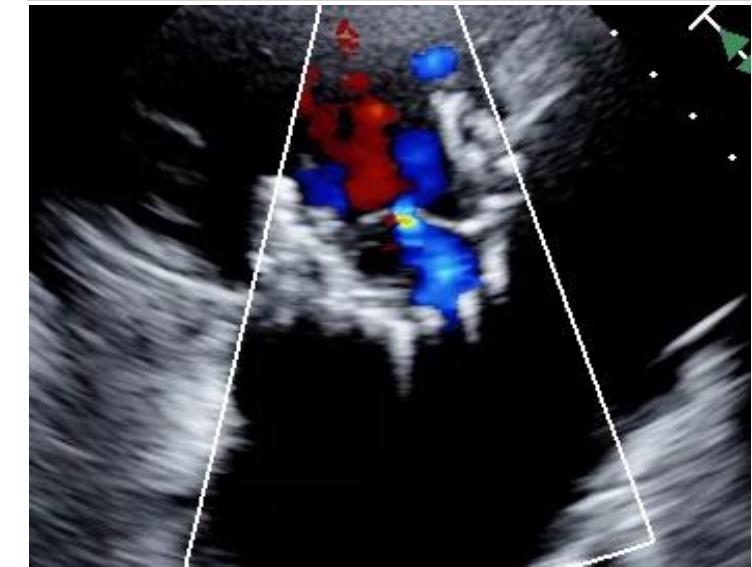
Unique valve design
engages leaflets, chords,
and annulus to achieve secure
placement

FOLLOW-UP

30-days post-Evoque



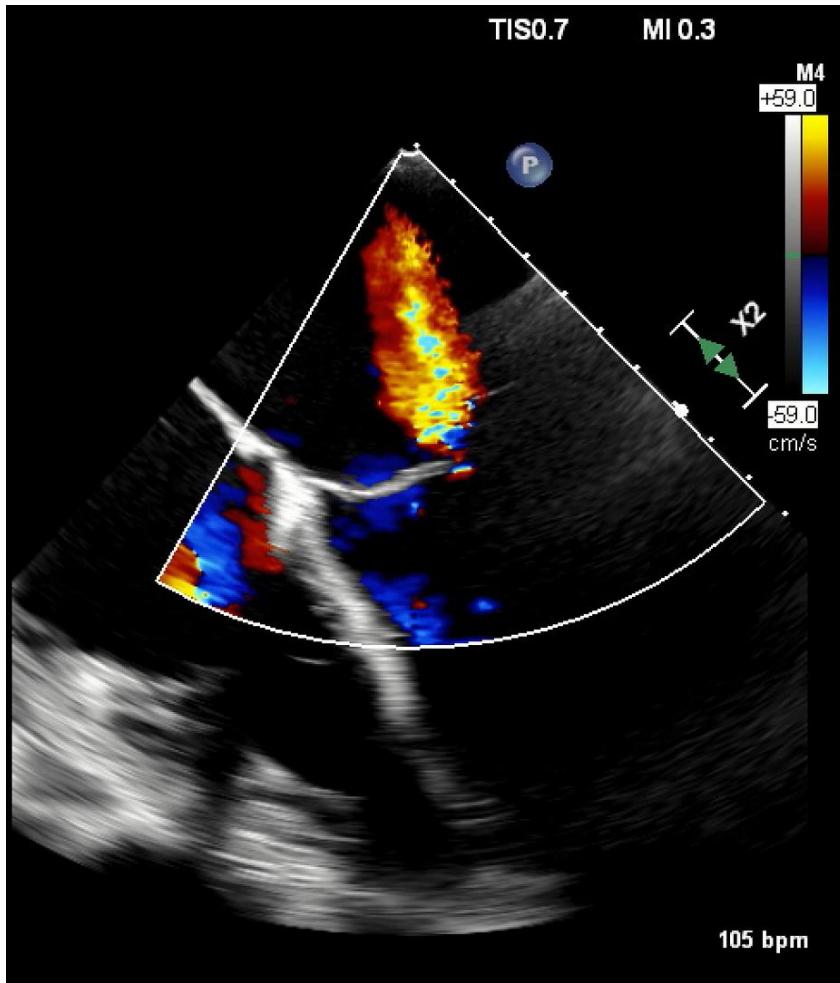
5-years post-Evoque



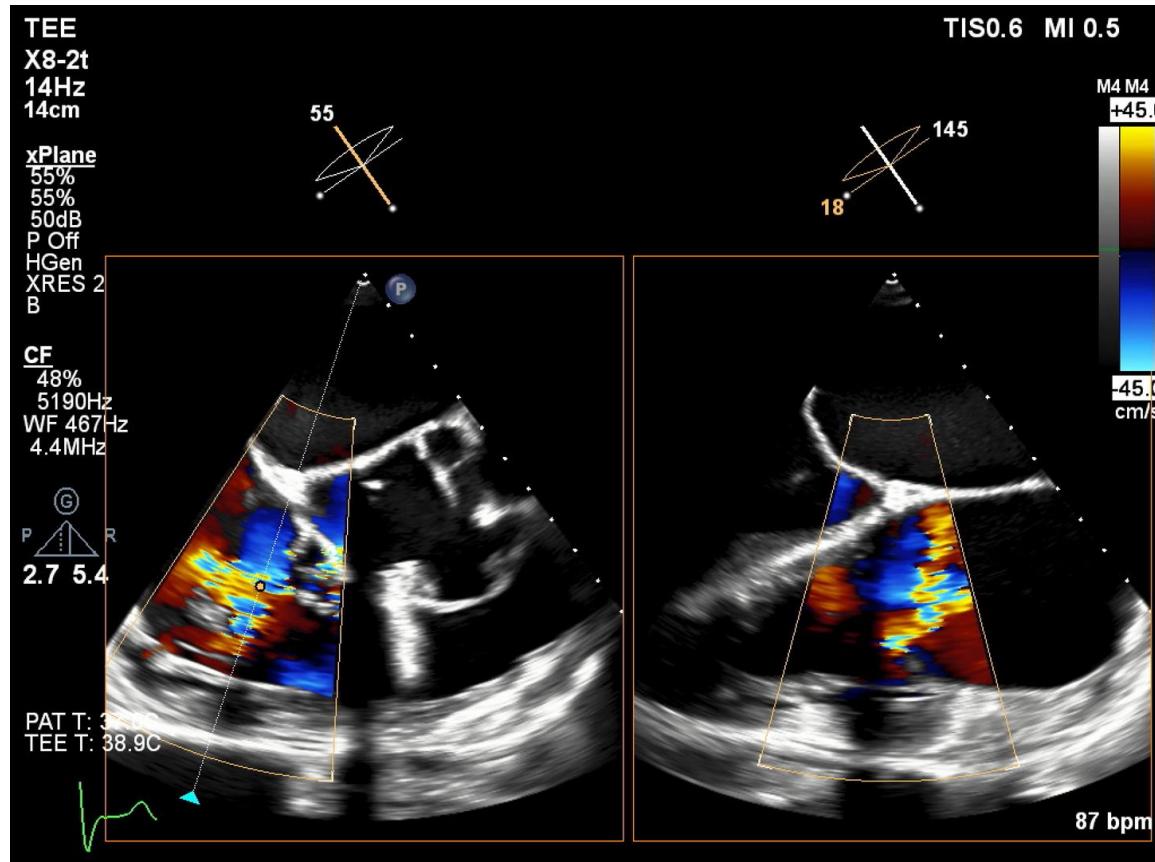
6-years post-M Dock



Mitral TEER (July 2024)

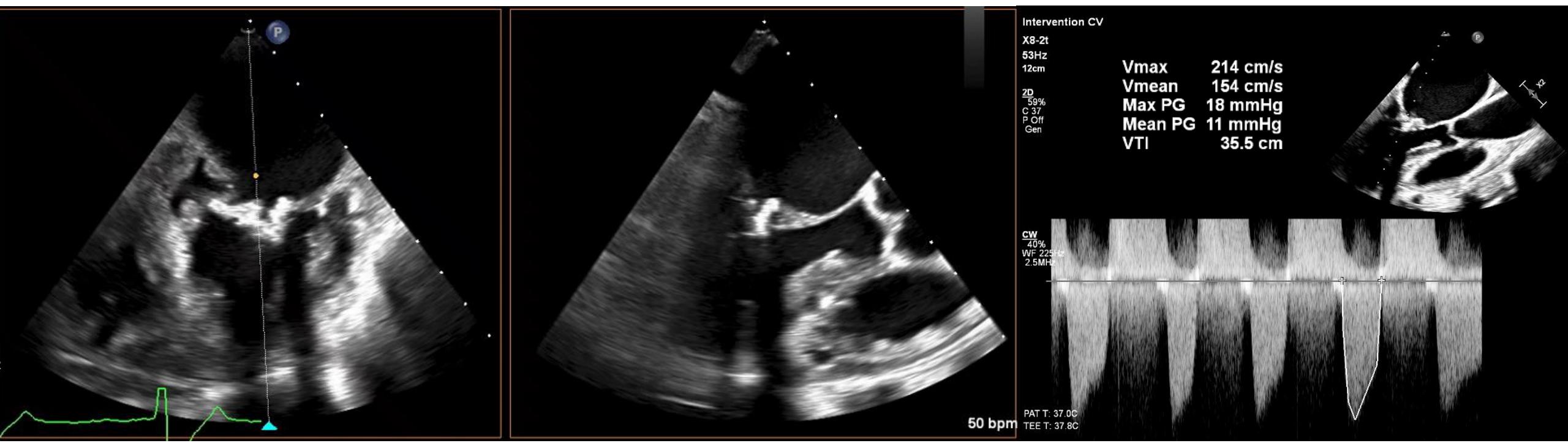


Evoque TTVR (November 2024)



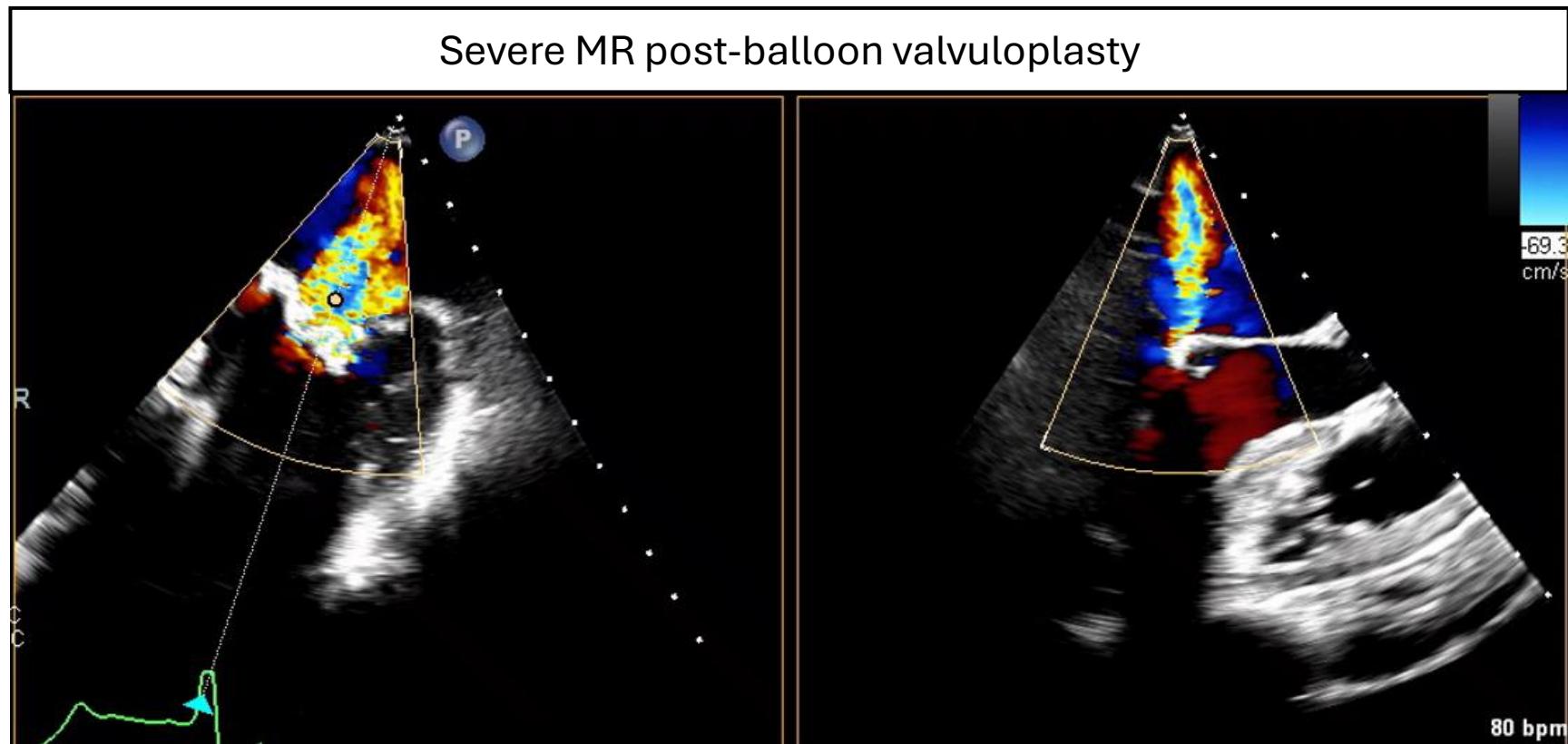
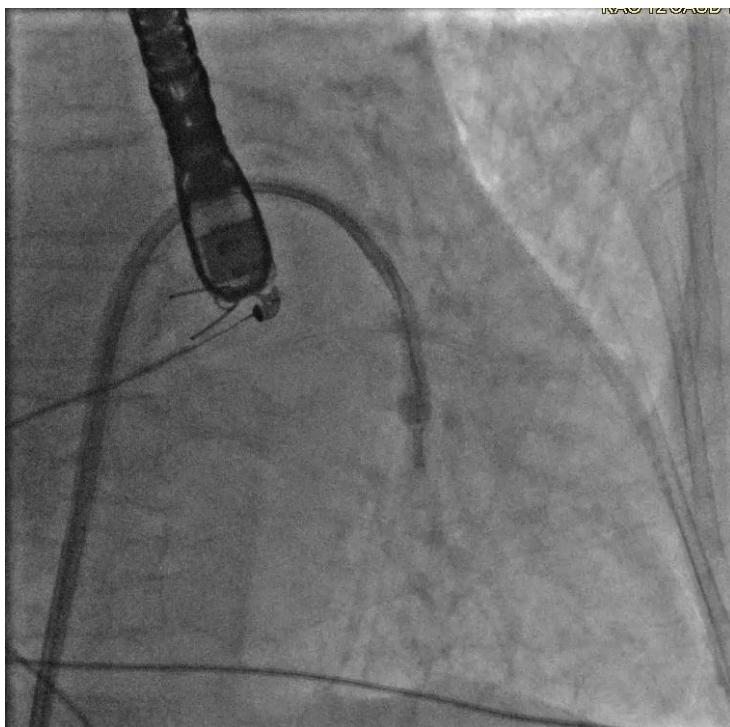
Rheumatic Mitral Stenosis (2025)

- 84-year-old female with severe mitral stenosis and mild to moderate MR
- Underwent a mitral commissurotomy in 1986 in India
- Balloon valvuloplasty in 2010 (also in India)
- Referred to us for a repeat balloon valvuloplasty



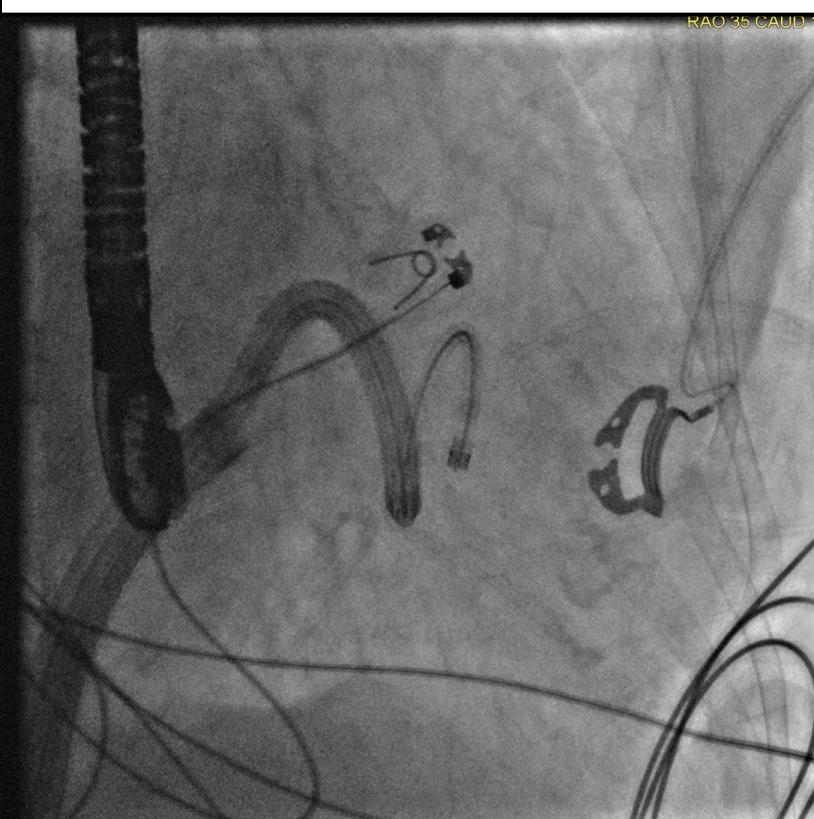
Balloon Mitral Valvuloplasty

- Anticipated risk of worsening MR
- Bailout strategy – Emergency compassionate use of Sapien M3 device

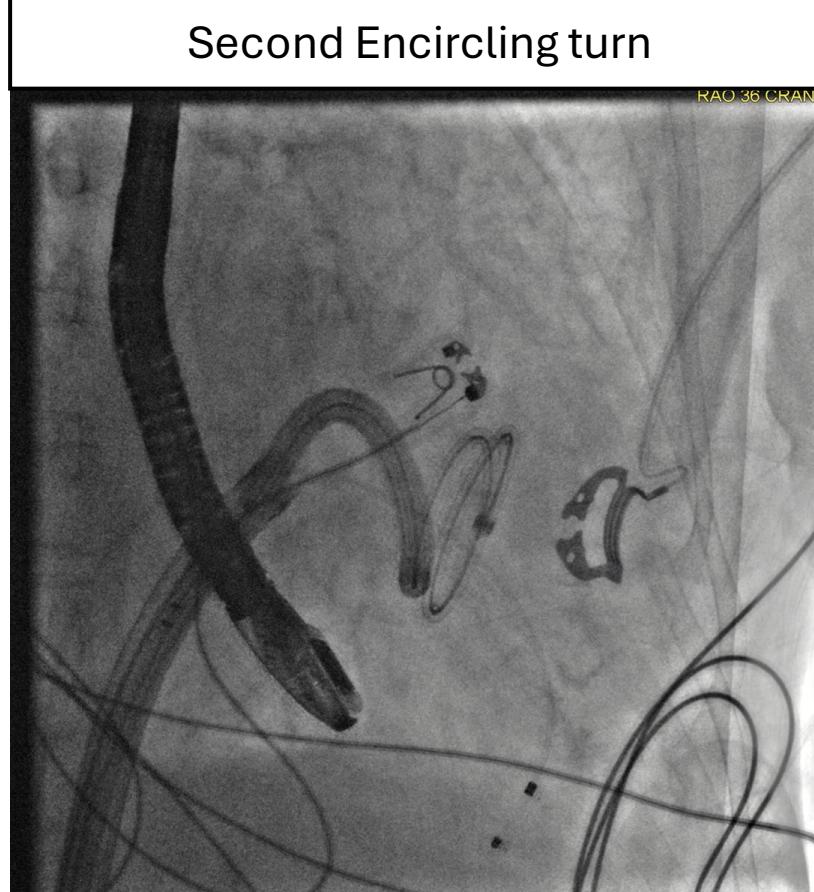


Sapien M3 Deployment

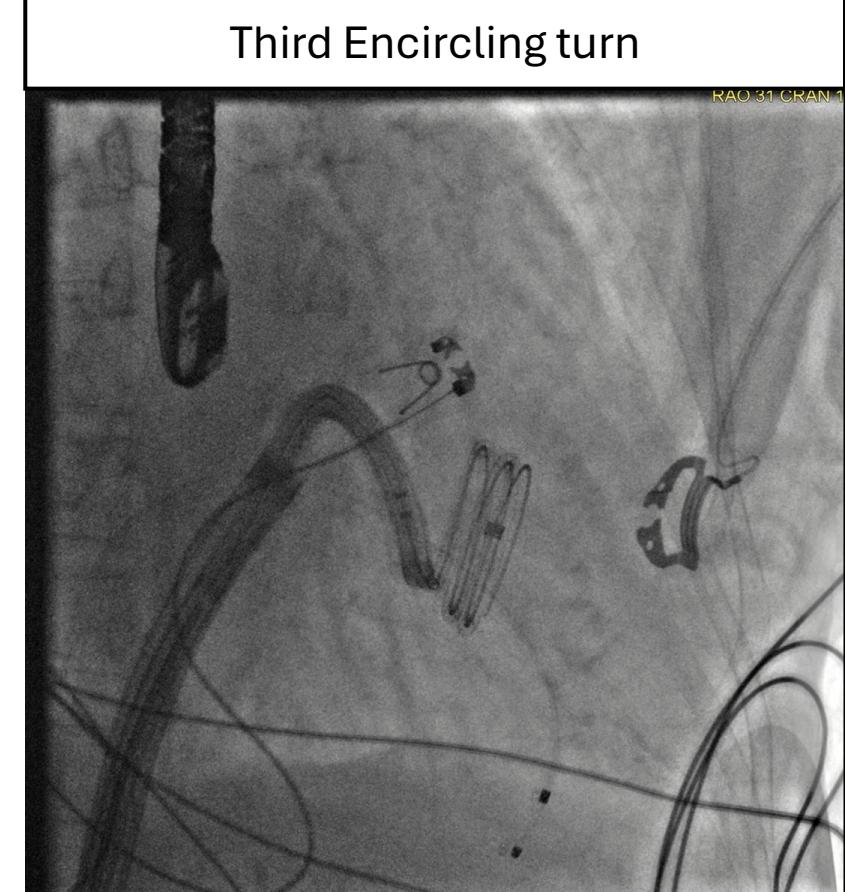
First Encircling turn



Second Encircling turn

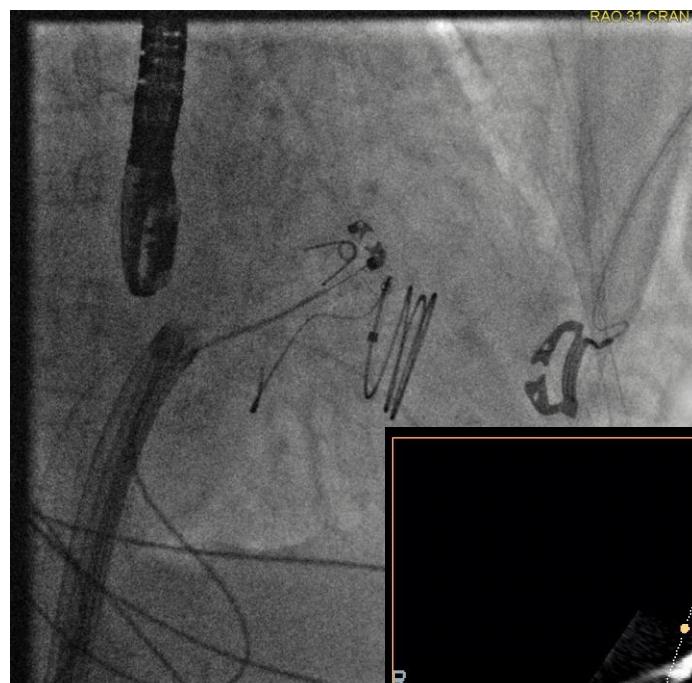
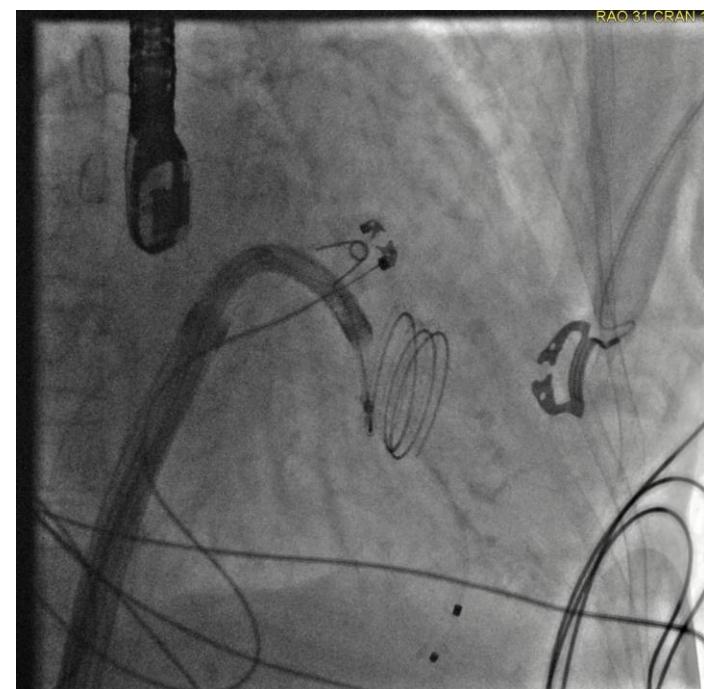


Third Encircling turn

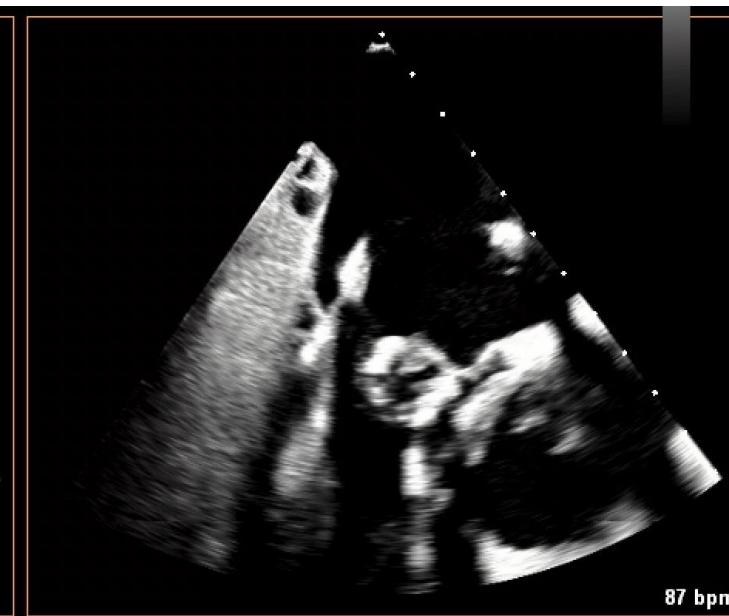
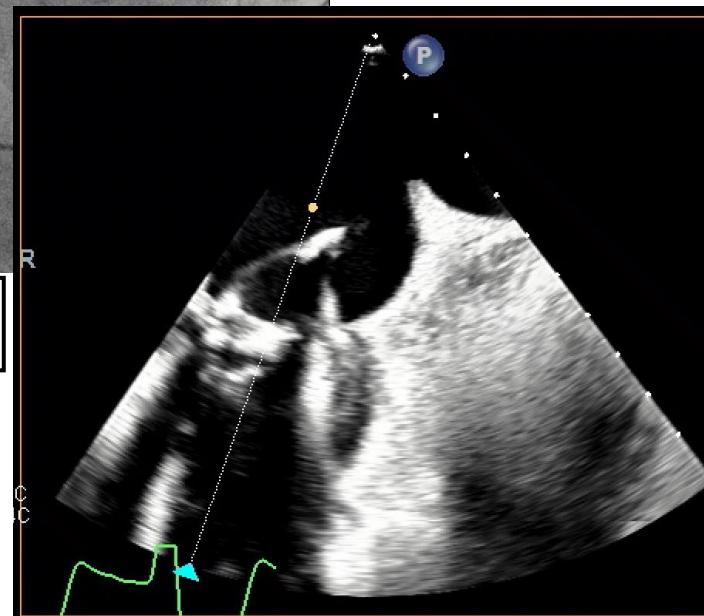


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Sapien M3 Deployment



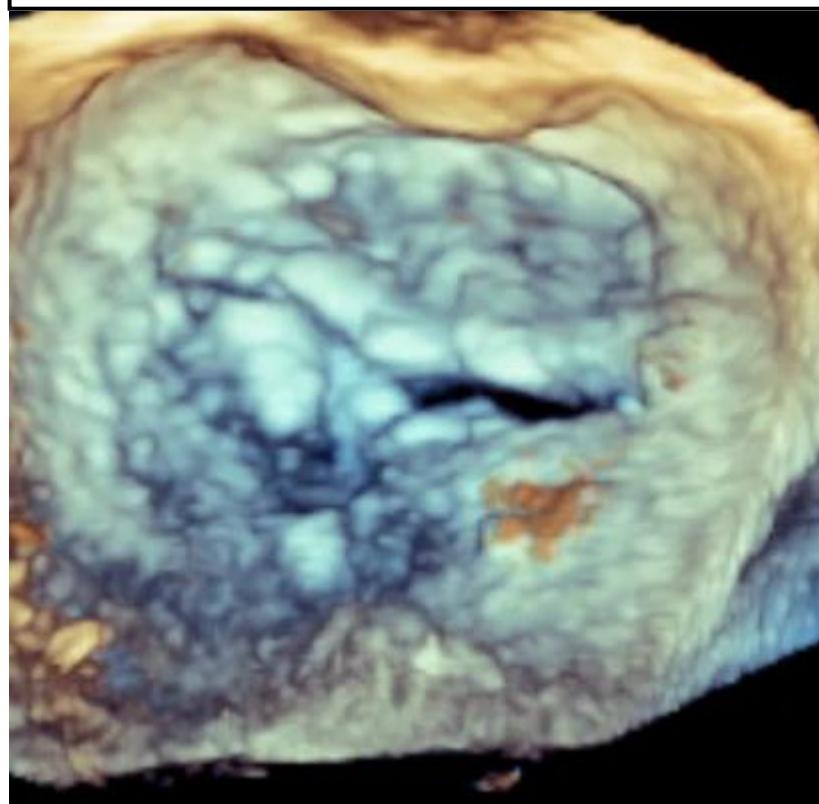
Revealing the atrial turn and deployment



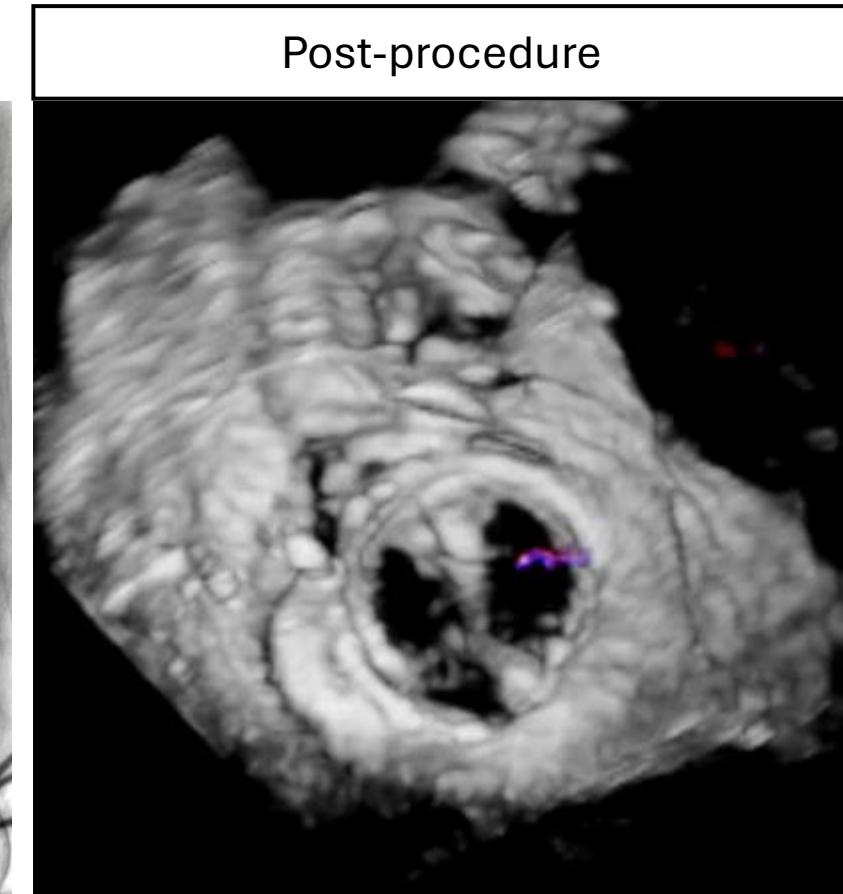
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Final Result

Baseline

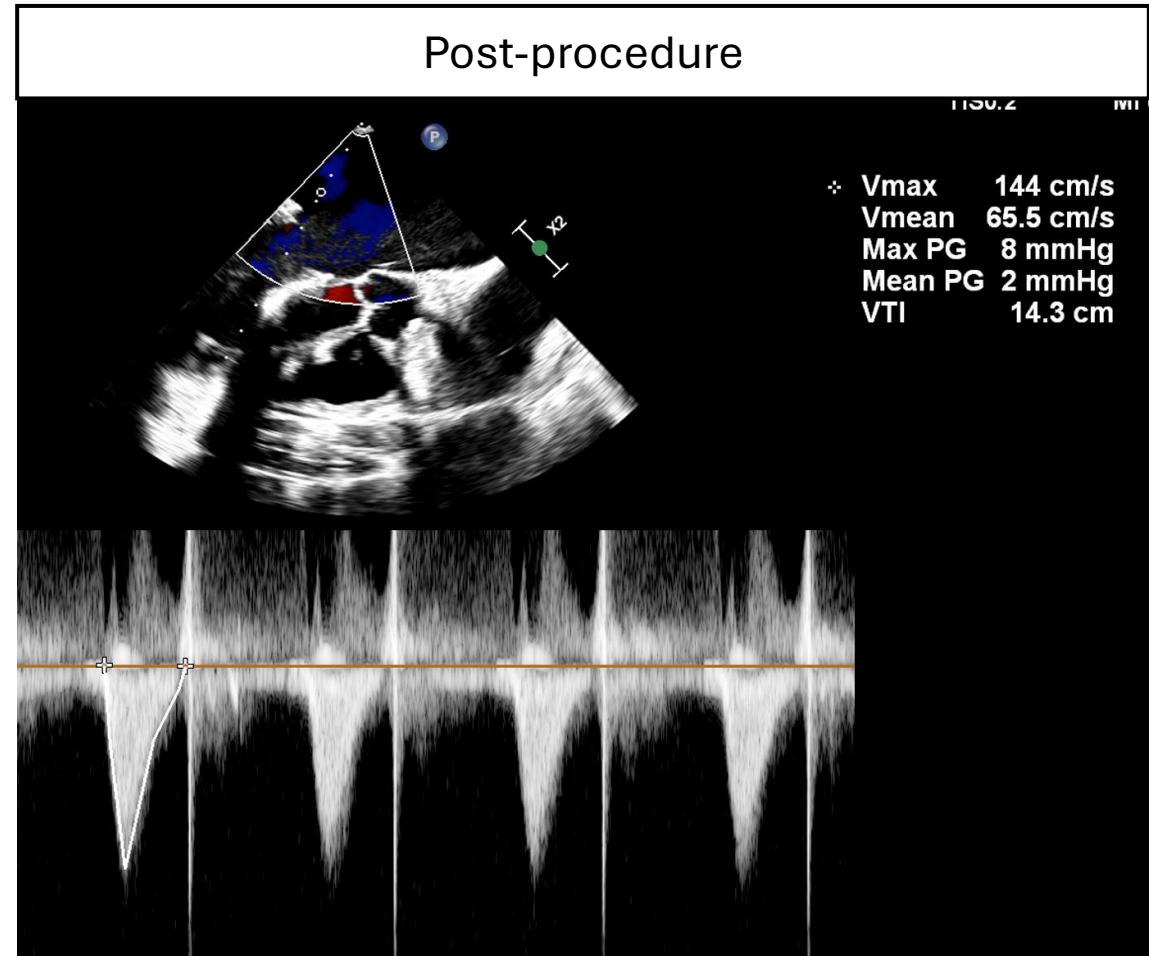
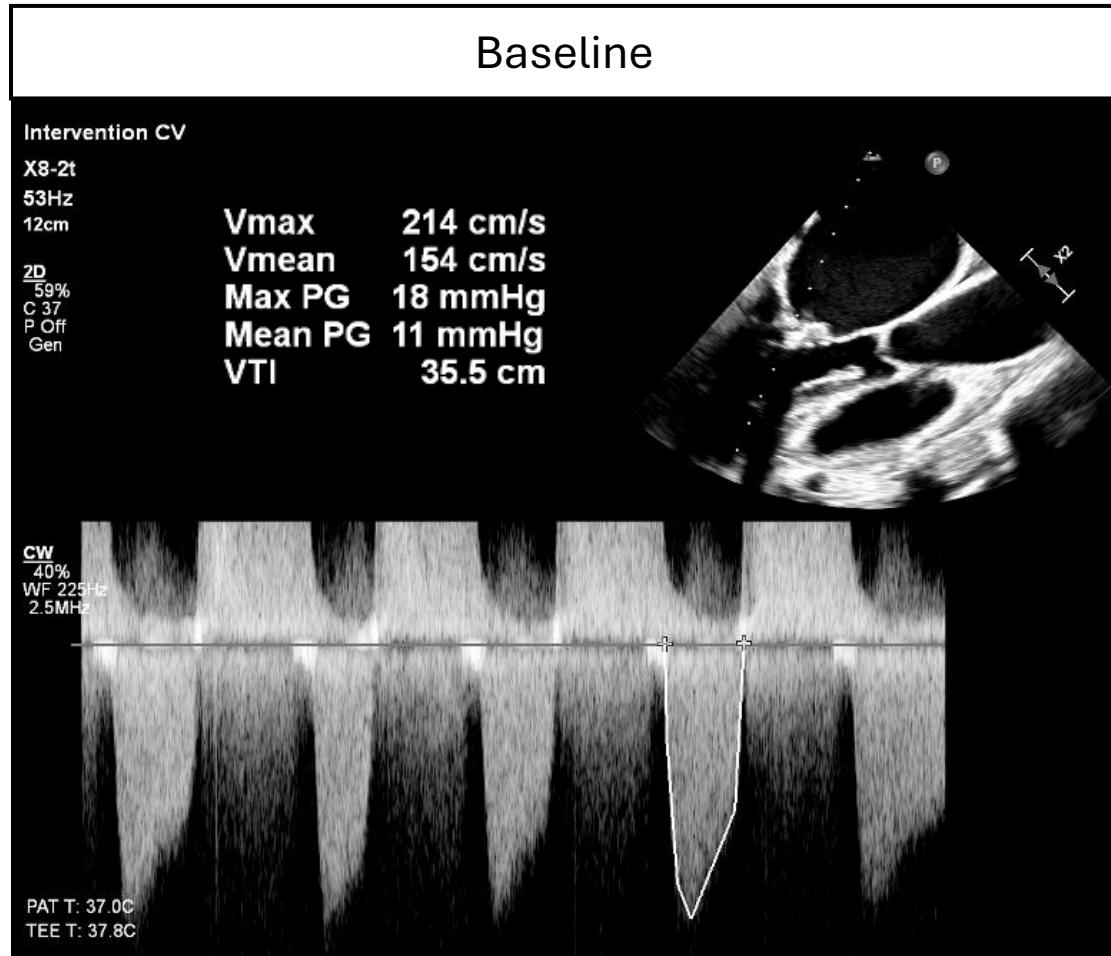


Post-procedure

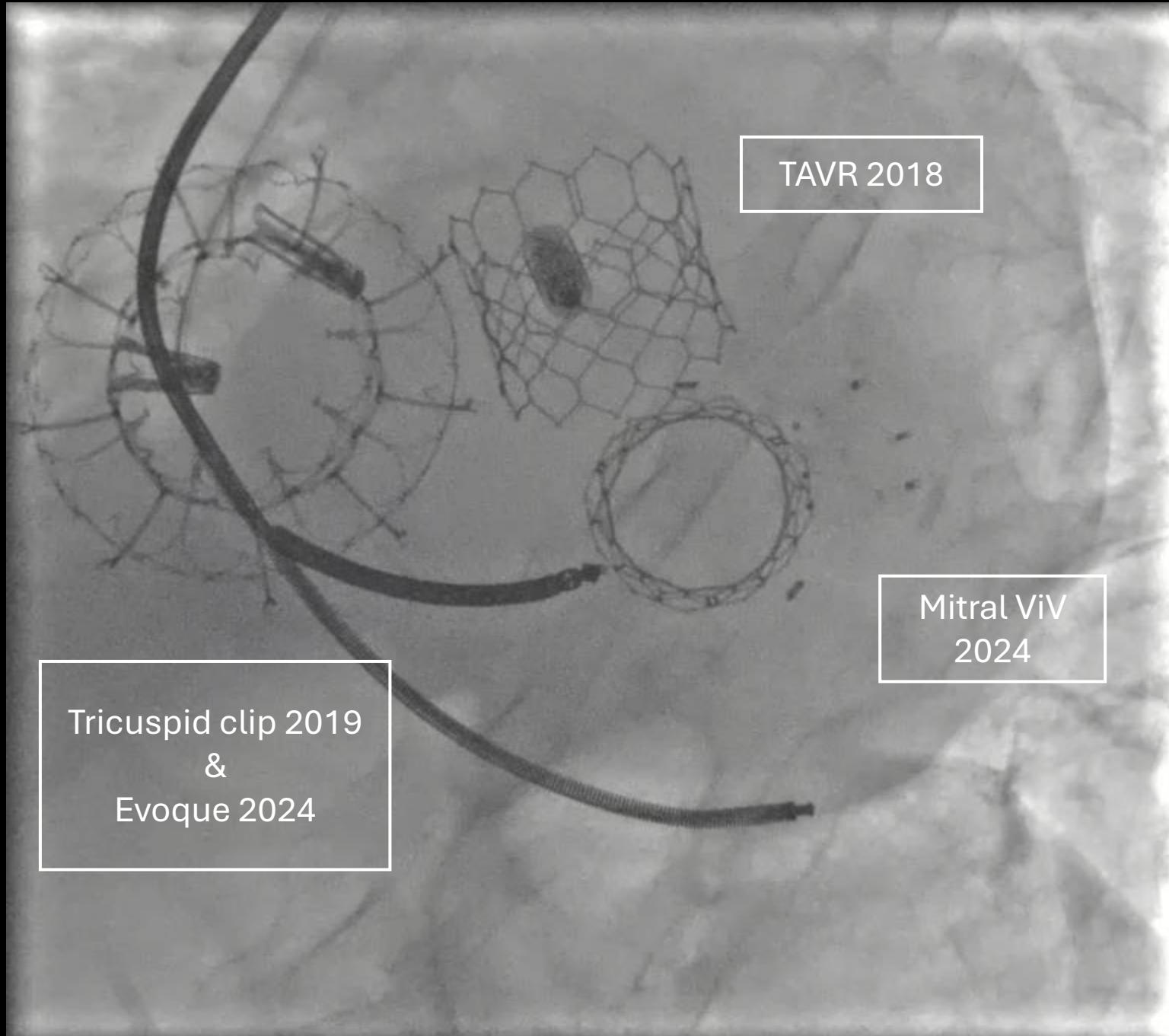


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Final Result



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