

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

Raj Makkar, MD
Cedars-Sinai Medical Center
Los Angeles, CA



TCT[®]

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)

Company Name(s)

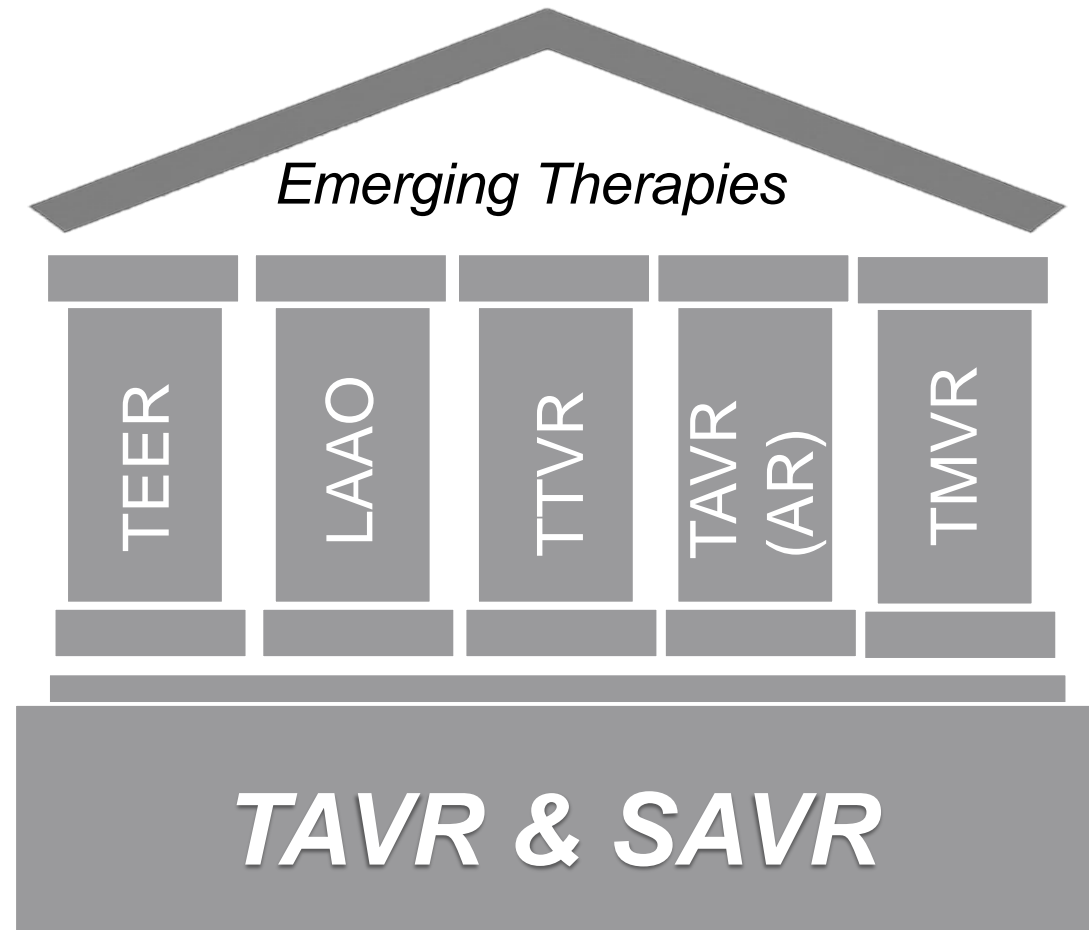
Company Name(s)

Company Name(s)

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

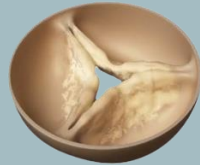


Clinical Evidence is Informing TAVR Treatment Strategies

PROGRESSION OF AORTIC STENOSIS



Mild



Moderate



**Severe
Asymptomatic**

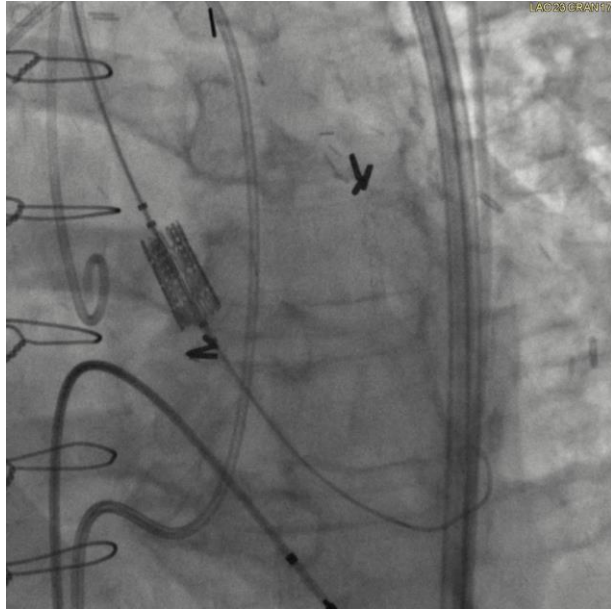
**Severe
Symptomatic**



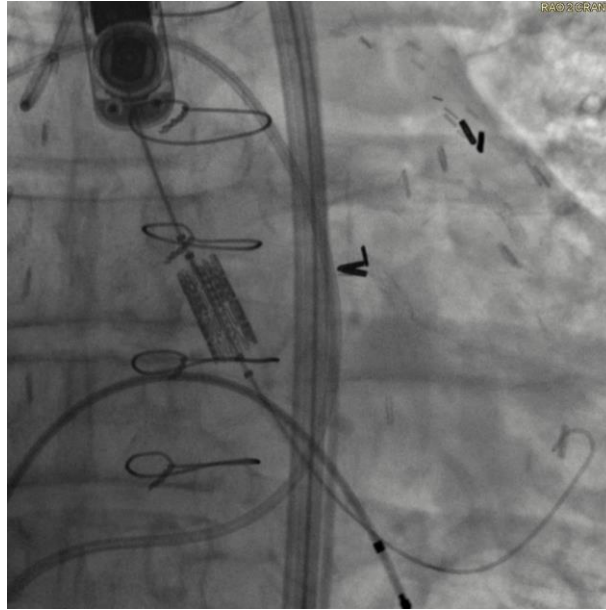
FIRST TAVR AT CEDARS-SINAI MEDICAL CENTER – November 26, 2007

Edwards-Sapien valve

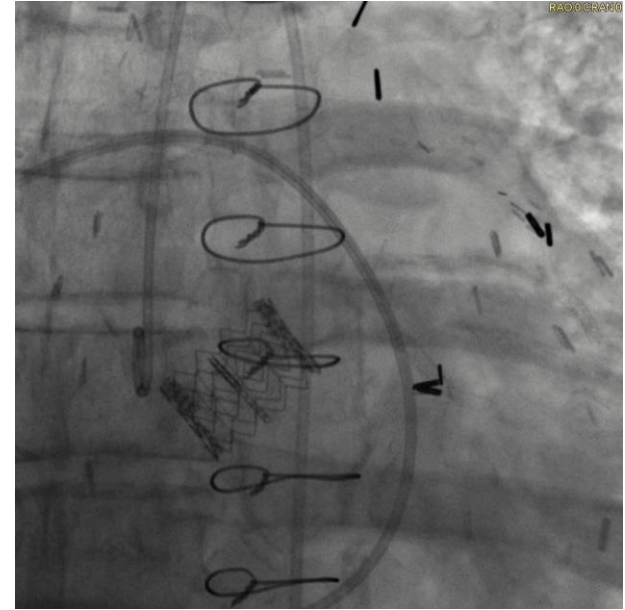
Positioning



Deployment



Final Result

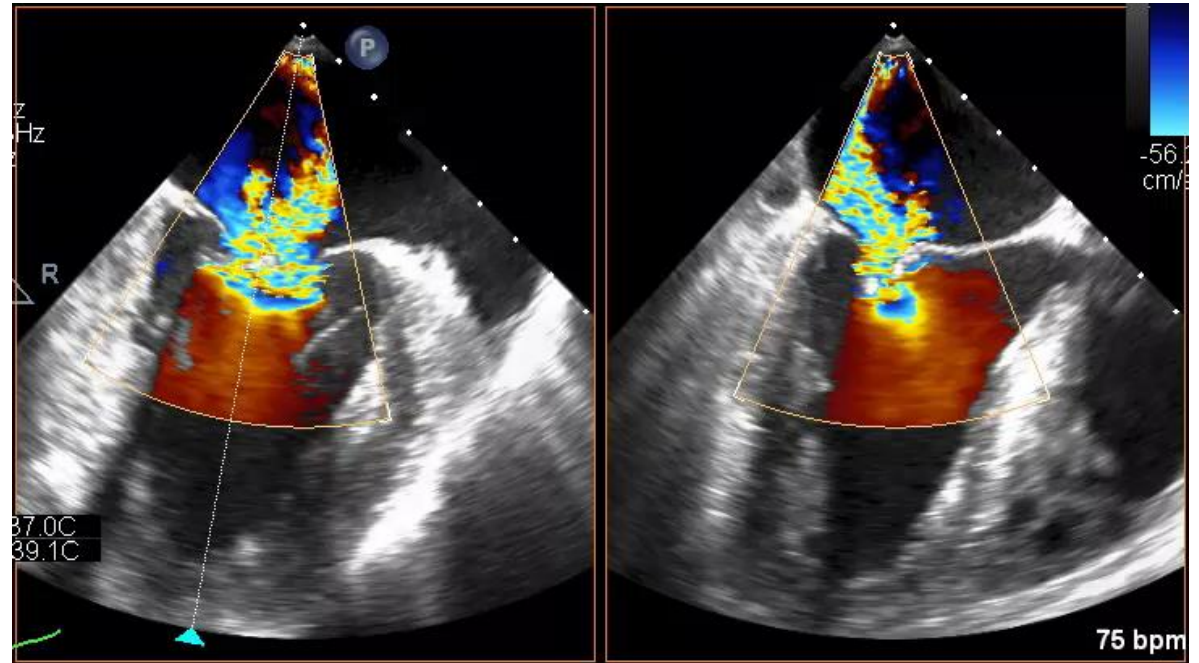


Clinical Presentation (January 2019)

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

Past medical history

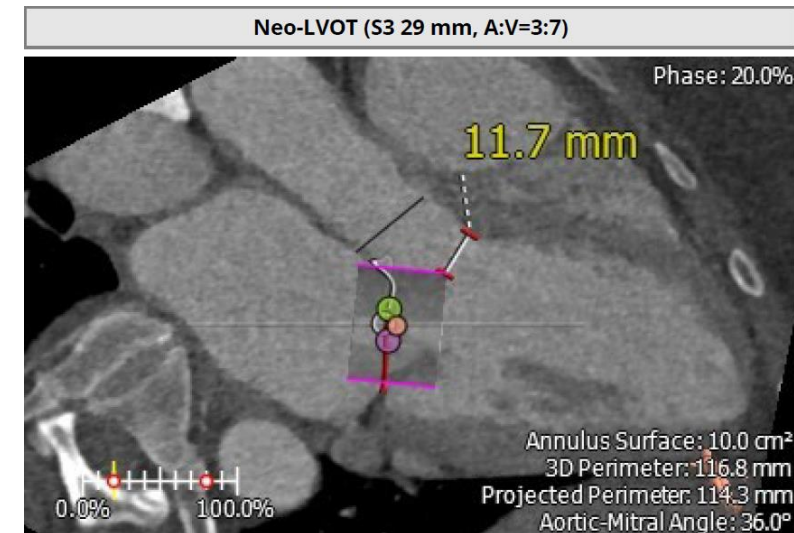
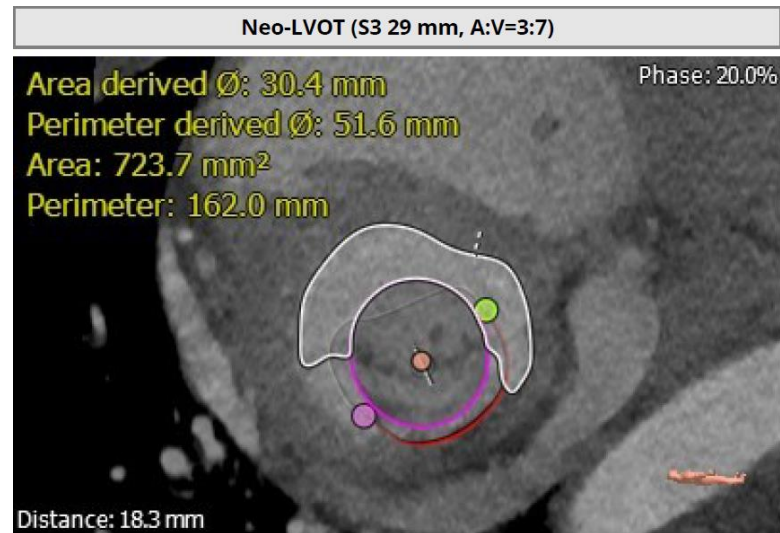
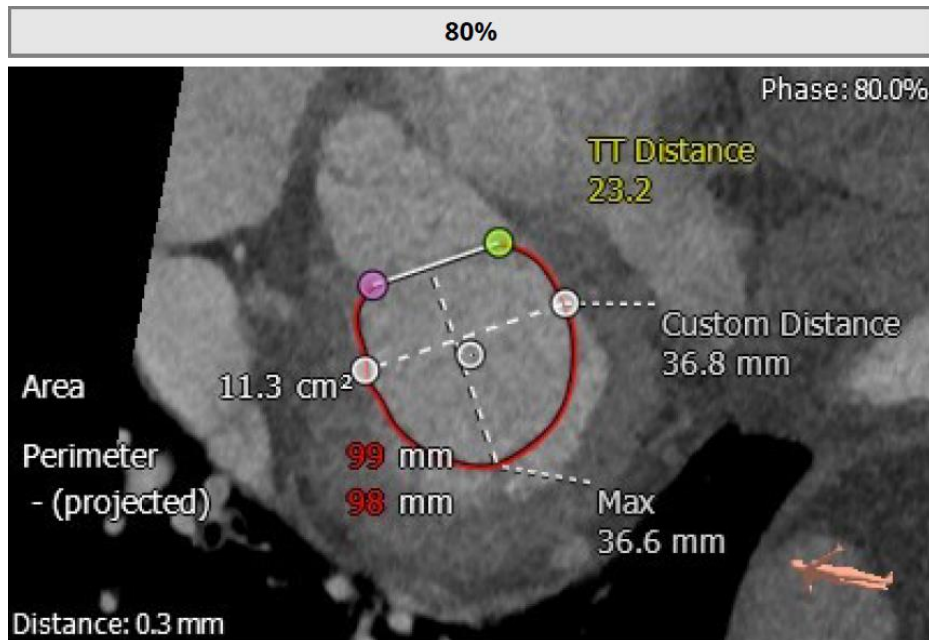
- Atrial fibrillation (on chronic AC)
- Type 2 Diabetes
- Hypertension
- Dyslipidemia
- CKD stage 3
- Morbid obesity (BMI 42 kg/m²)



Severe Functional Mitral Regurgitation

CASE IMAGING

COMPUTED TOMOGRAPHY



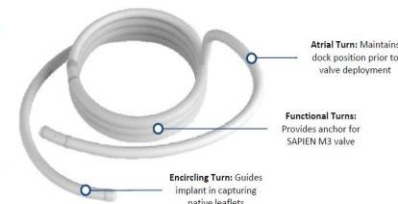
Annulus suitable for 29 mm Sapien M3
Low-risk of LVOT obstruction
Favorable aorto-mitral angle

Edwards SAPIEN M3 Dock

Nitinol dock facilitates:

- Anchoring of 29mm SAPIEN M3 valve
- Low profile, transseptal delivery and retrievability
- Allows treatment of a wide range of annulus sizes

Dock encircles native mitral leaflets to secure system



Edwards SAPIEN M3 Valve

Leverages SAPIEN 3 valve tissue and frame

Knitted PET skirt aids in sealing between native leaflets and dock

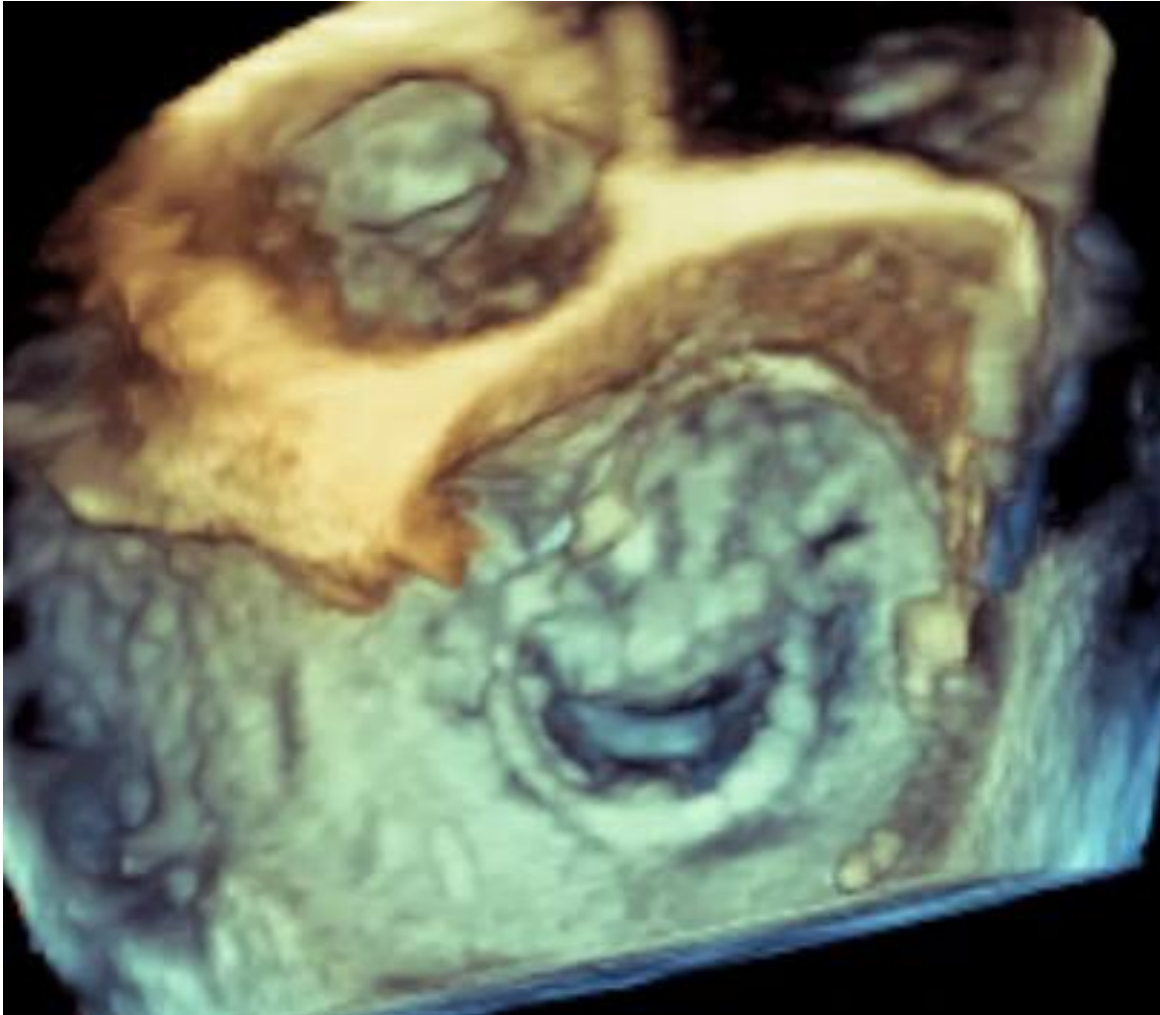
29 mm valve

20F eSheath compatibility

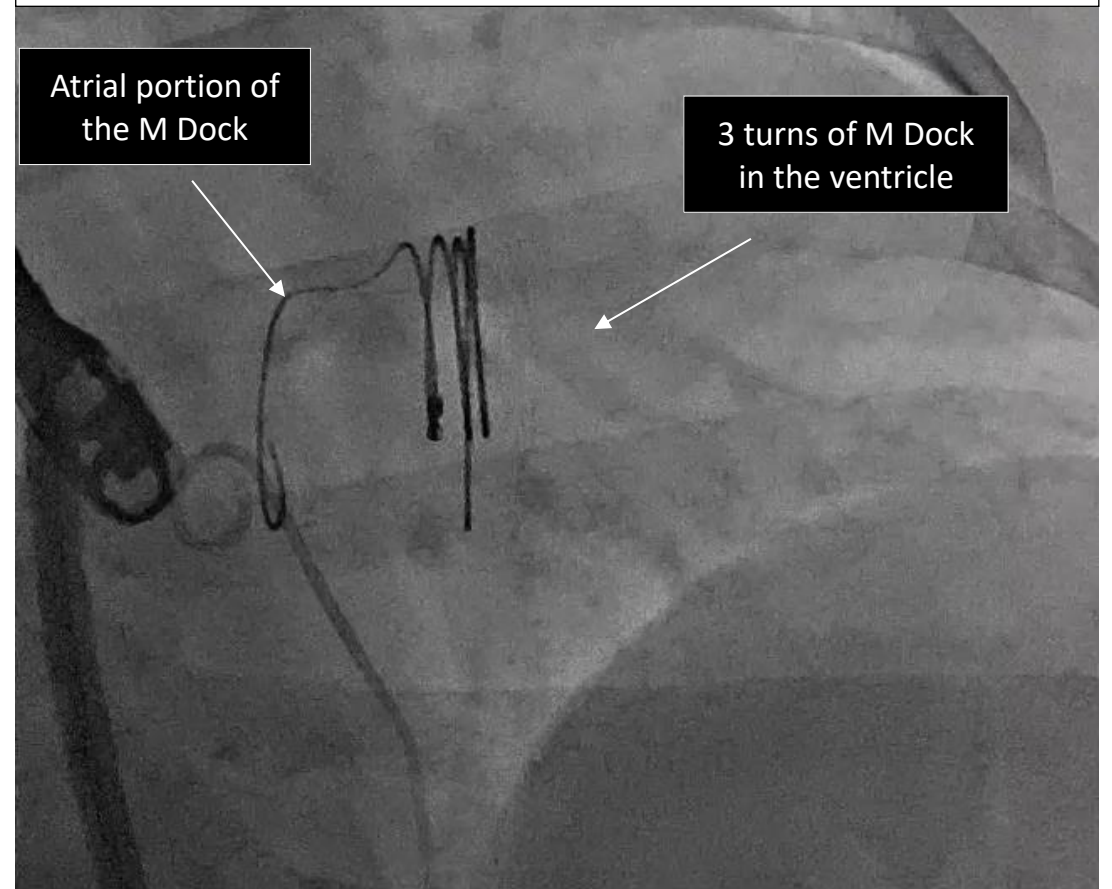


Caution: Investigational device. Limited by United States law to investigation use.

M Dock Release



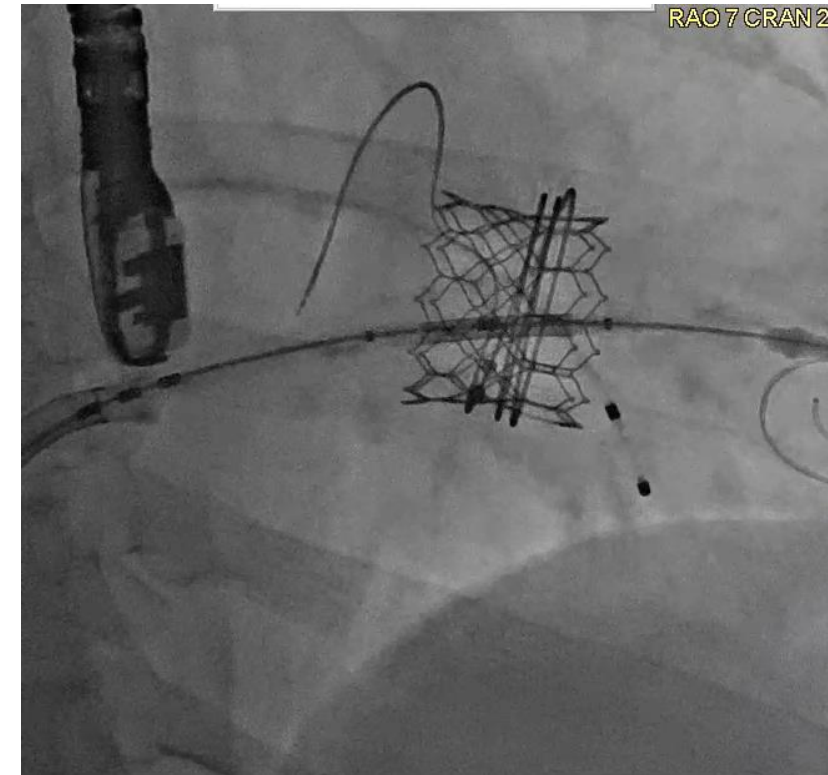
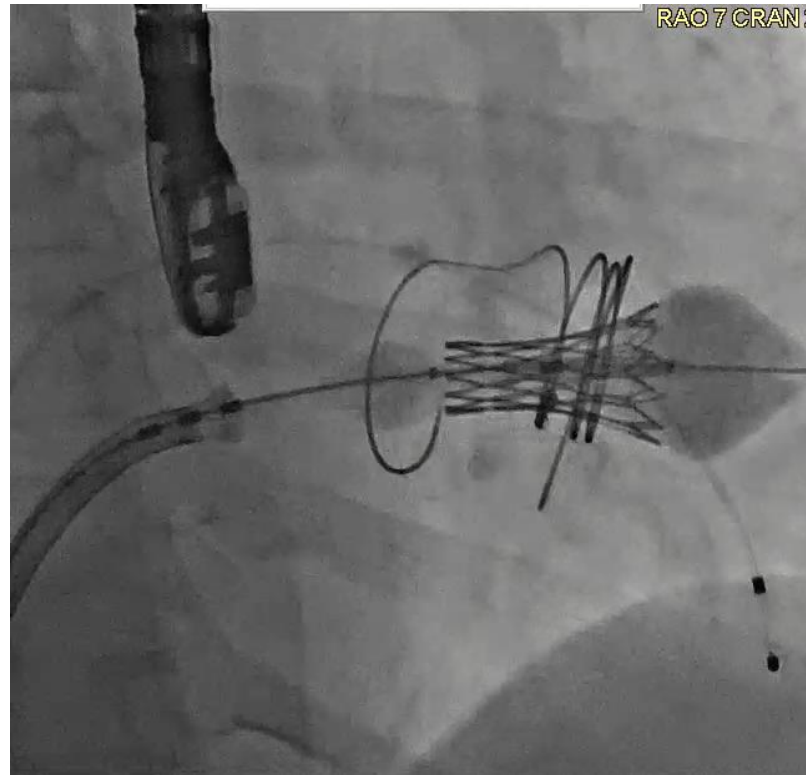
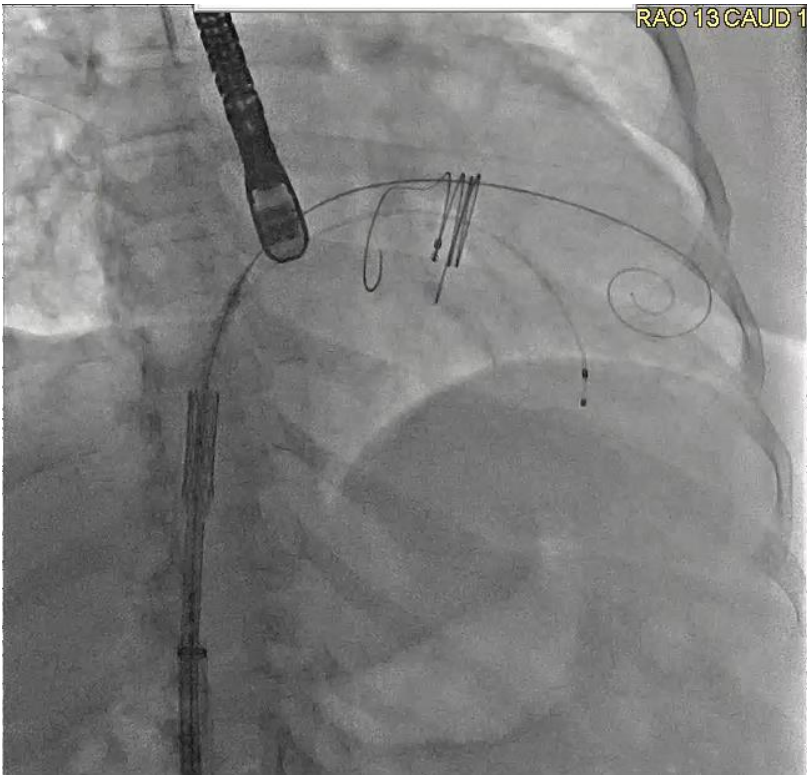
Mdock released from the delivery system



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

PROCEDURE

STEP 2: Deployment of Sapien M3 valve

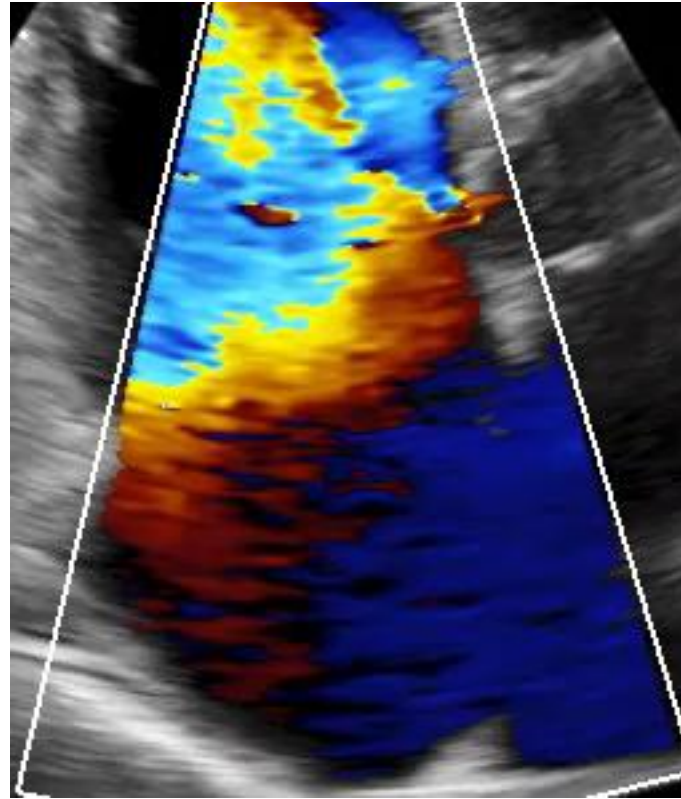
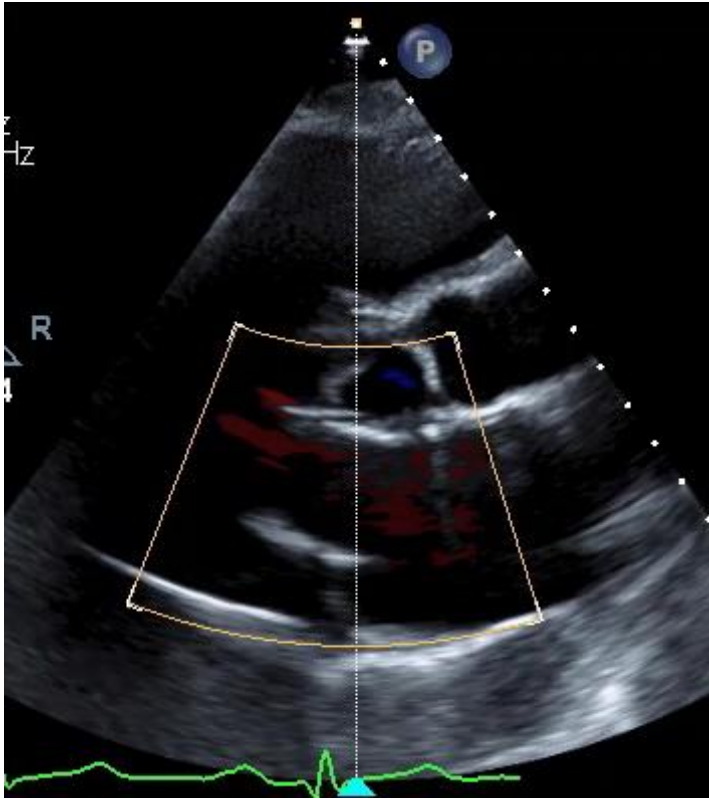


Sapien M3 deployment under rapid pacing

Post-dilatation with +4 cc

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

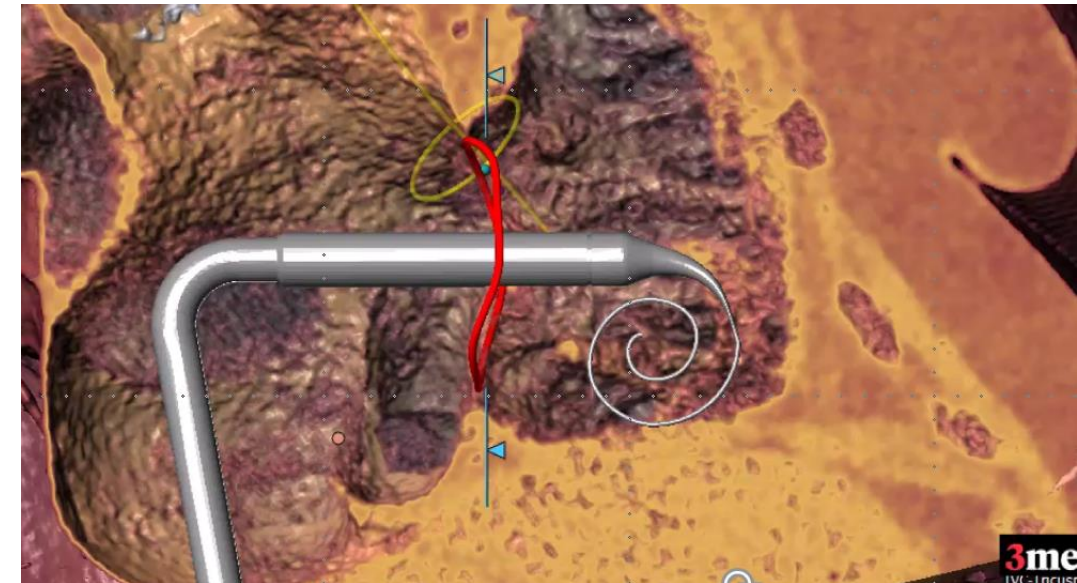
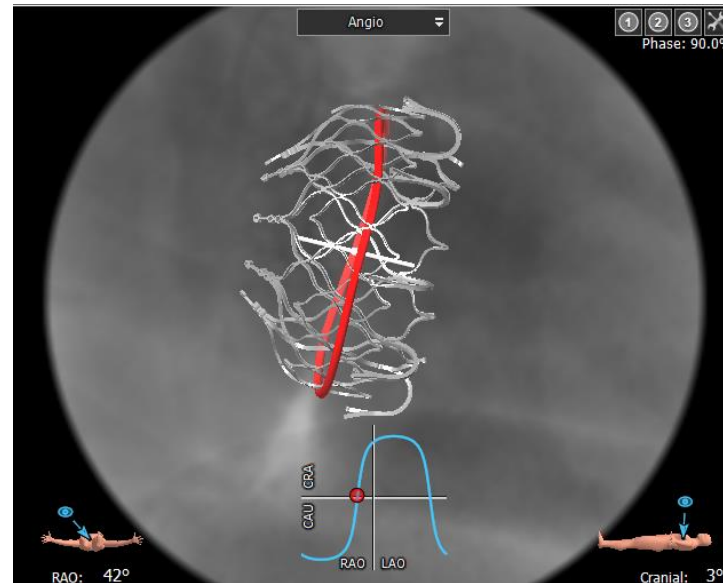
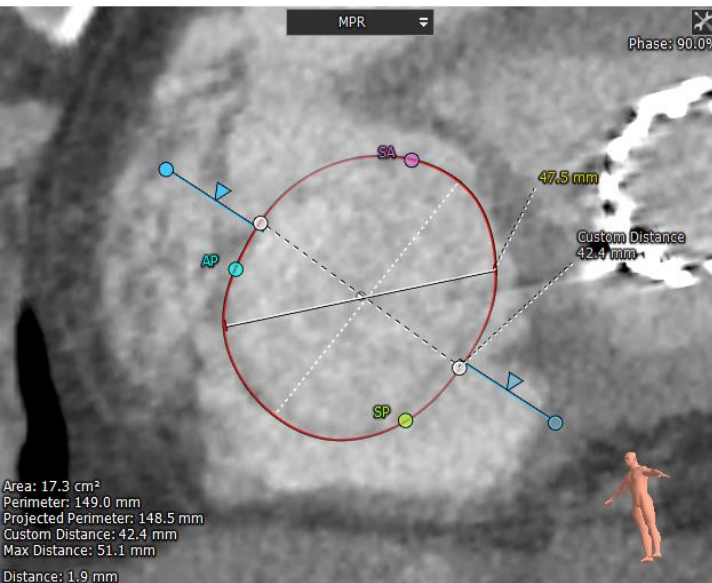
1-YEAR FOLLOW-UP – NYHA Class III symptoms with severe dyspnea on exertion and Edema (June 2020)



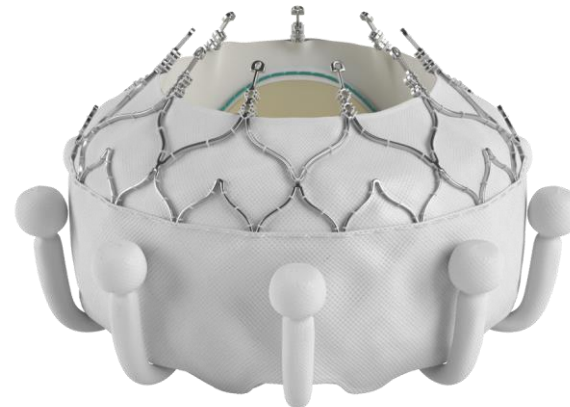
No central or mitral paravalvular leak
Severe TR (EROA: 0.62, TR Regurgitant Volume: 95 mL/beat)

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

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

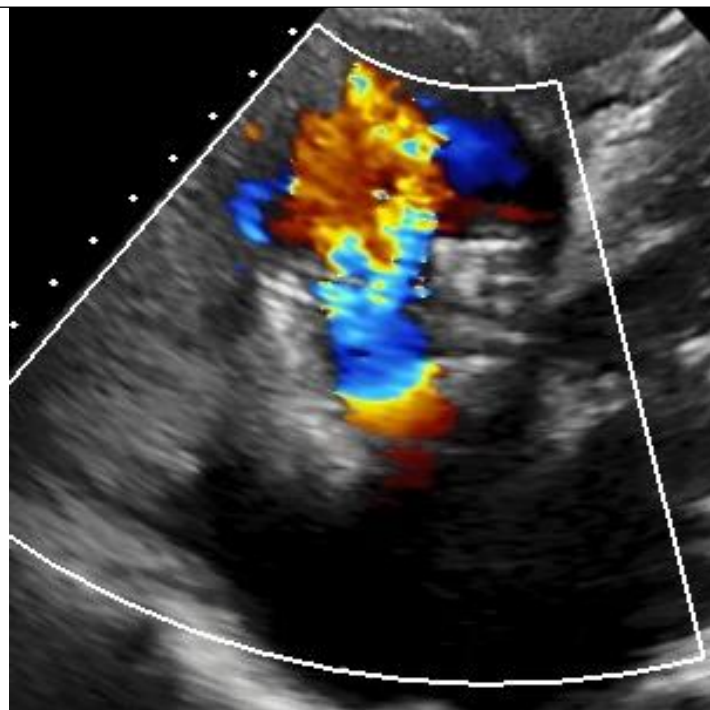


Unique valve design

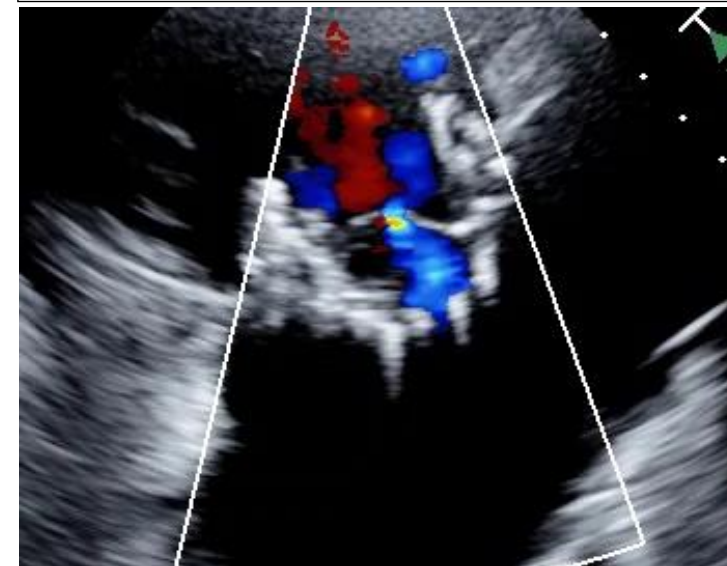
engages leaflets, chords,
and annulus to achieve secure
placement

FOLLOW-UP

30-days post-Evoque



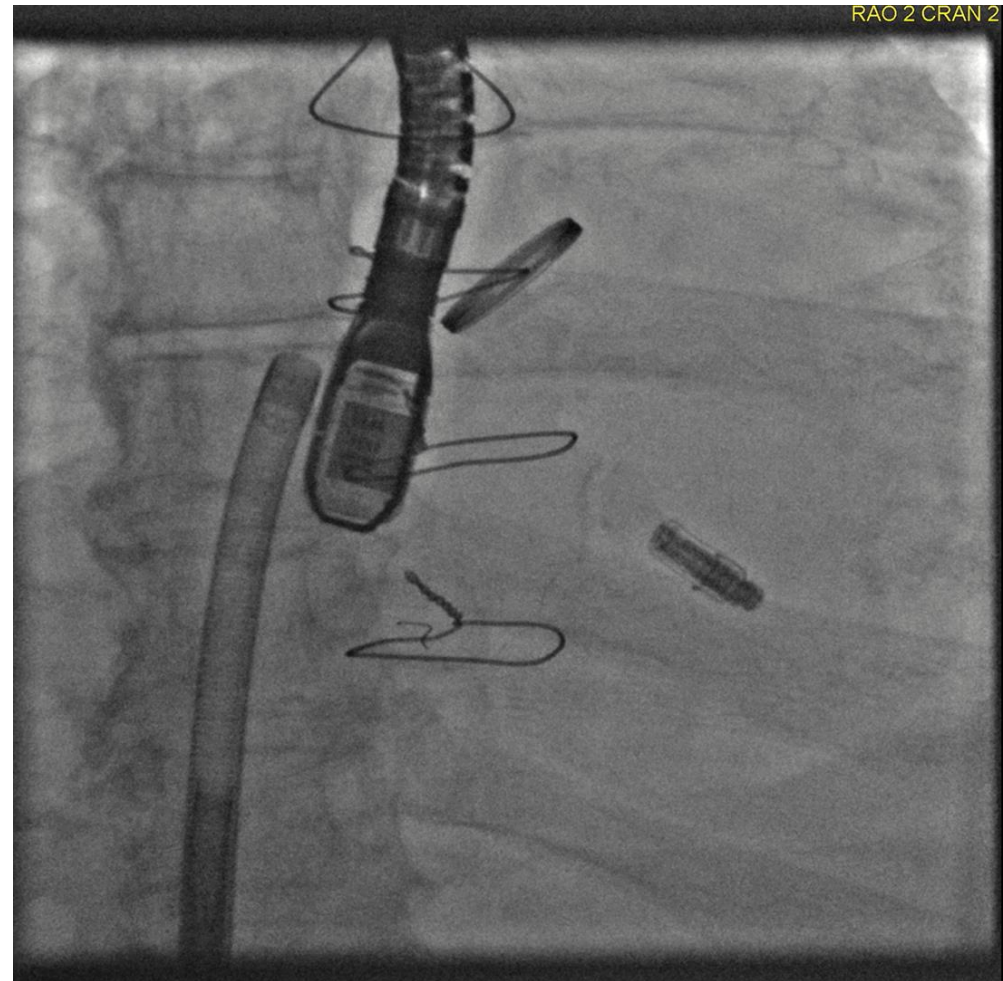
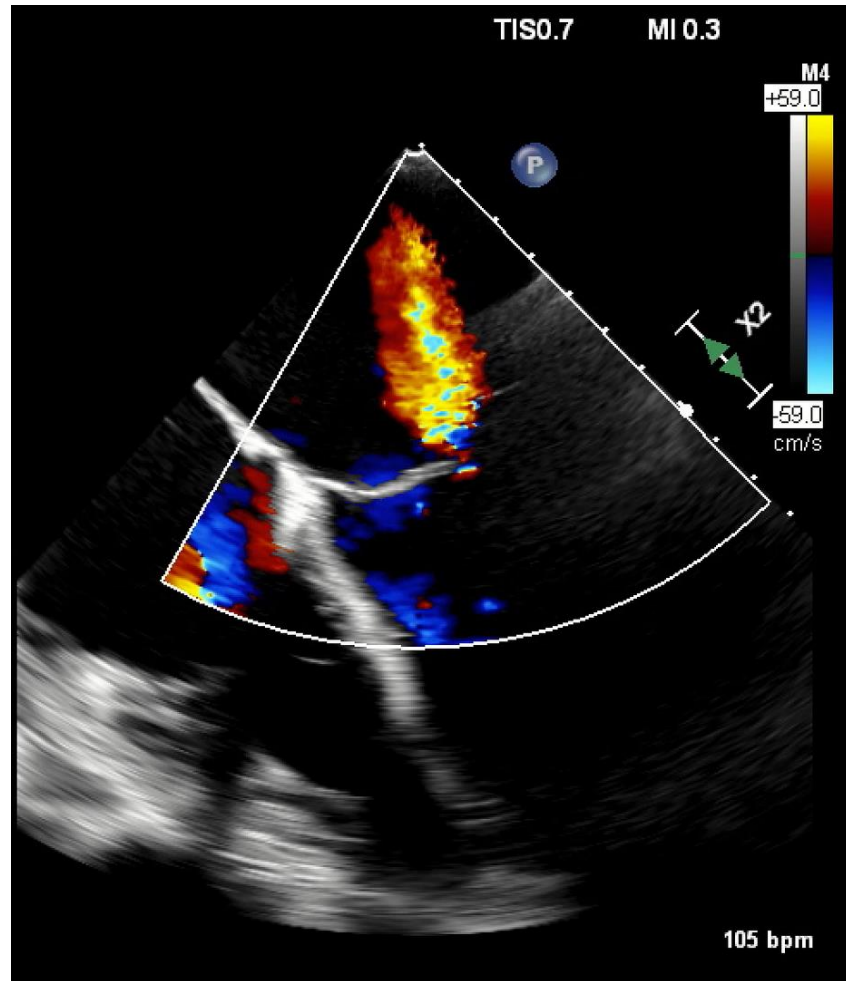
5-years post-Evoque



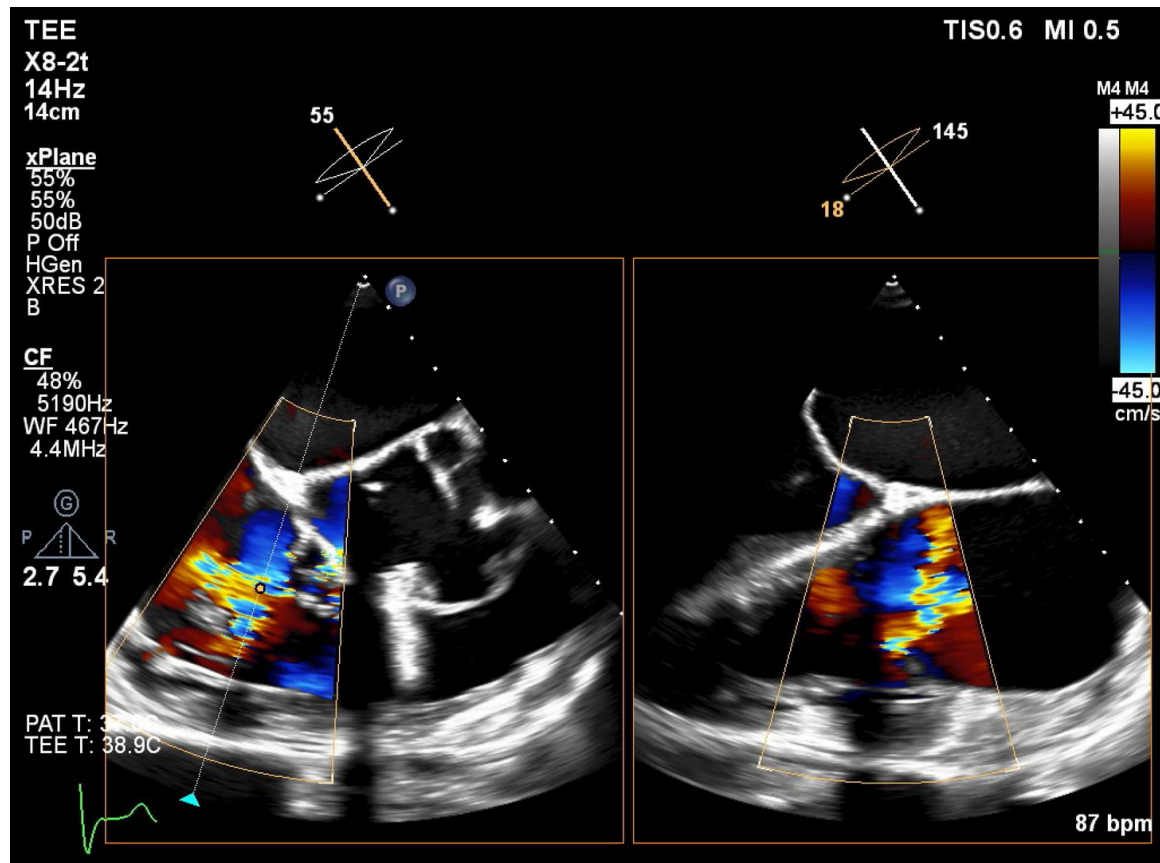
6-years post-M Dock



Mitral TEER (July 2024)

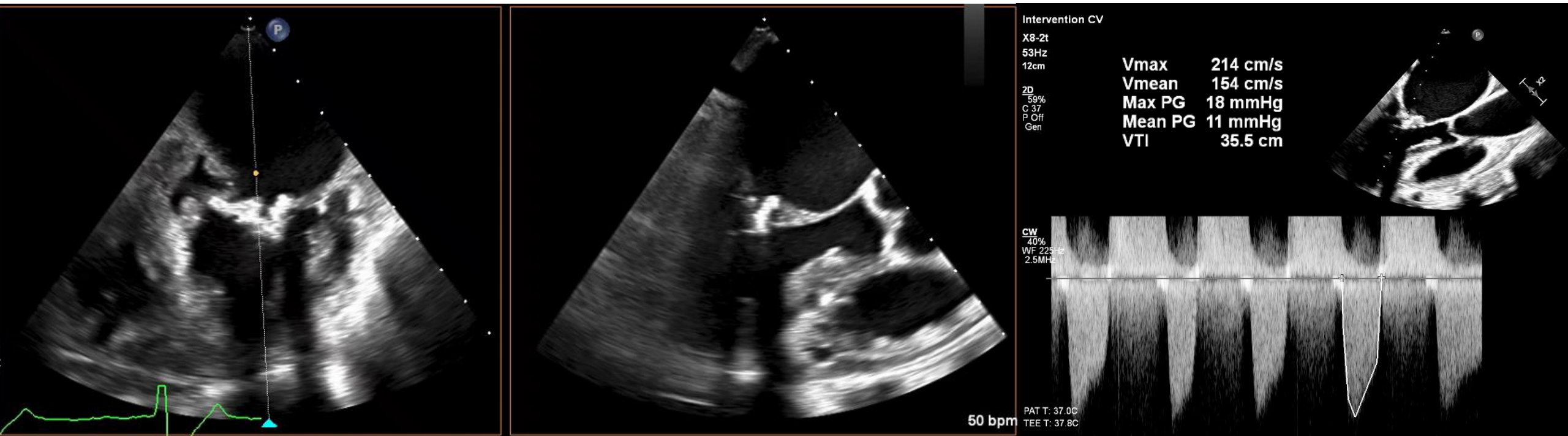


Evoque TTVR (November 2024)



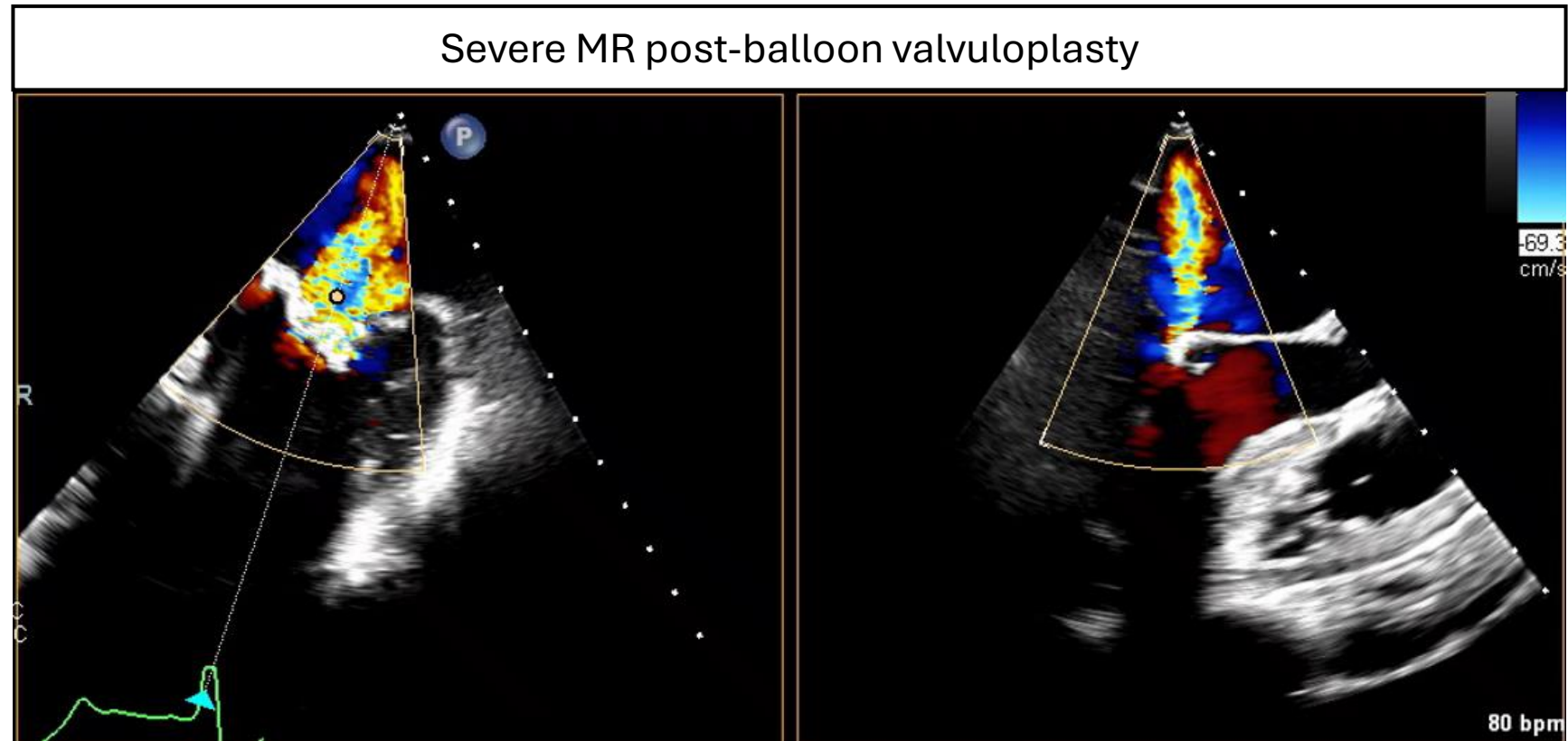
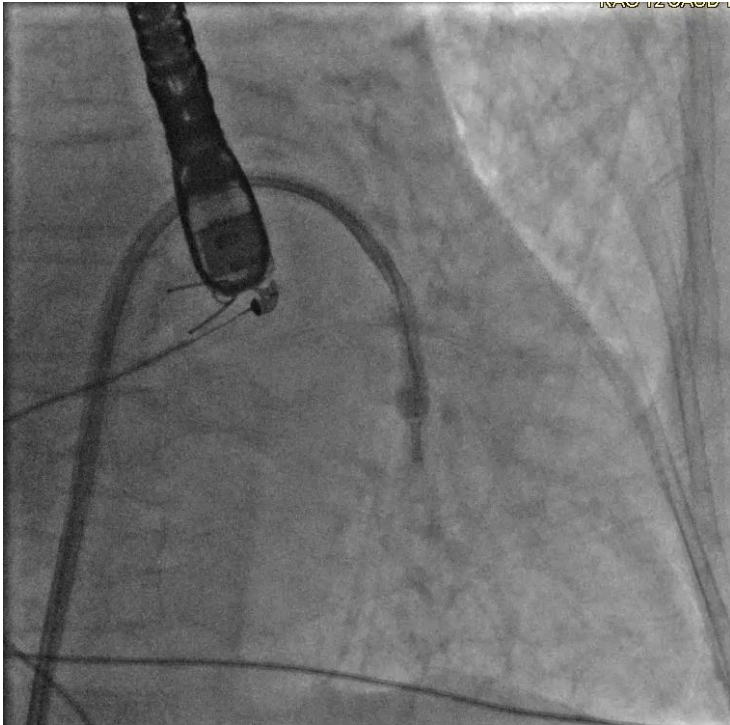
Rheumatic Mitral Stenosis (2025)

- 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



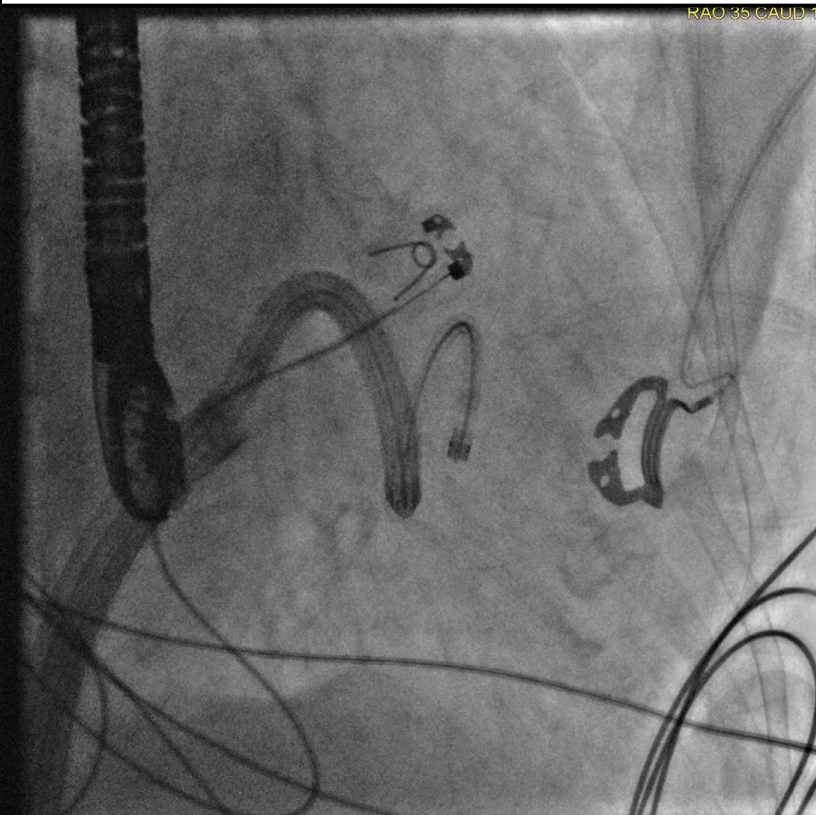
Balloon Mitral Valvuloplasty

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



Sapien M3 Deployment

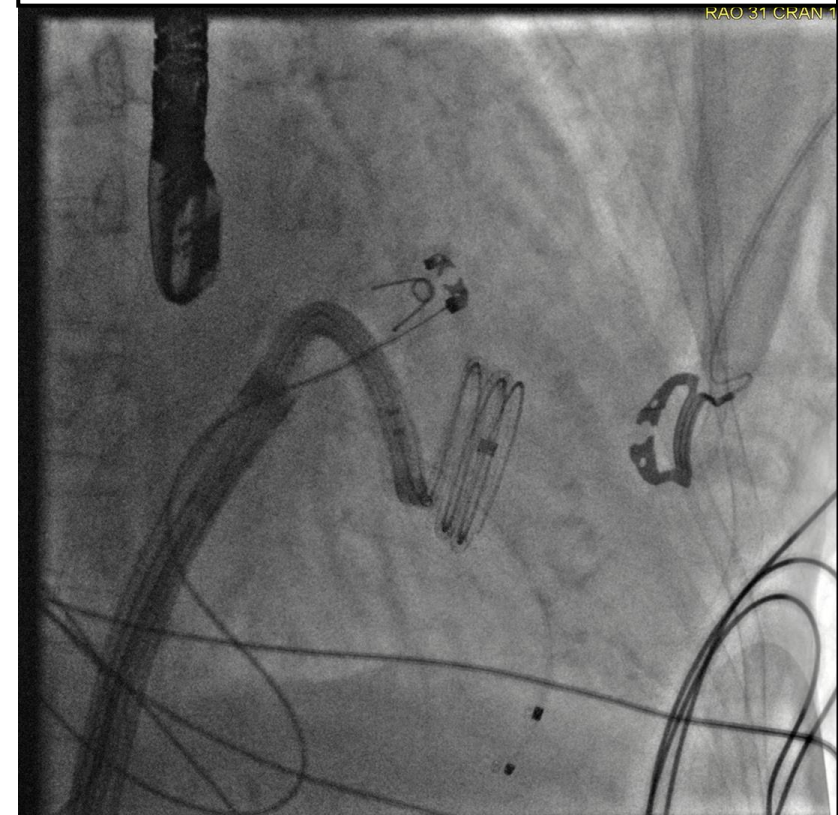
First Encircling turn



Second Encircling turn

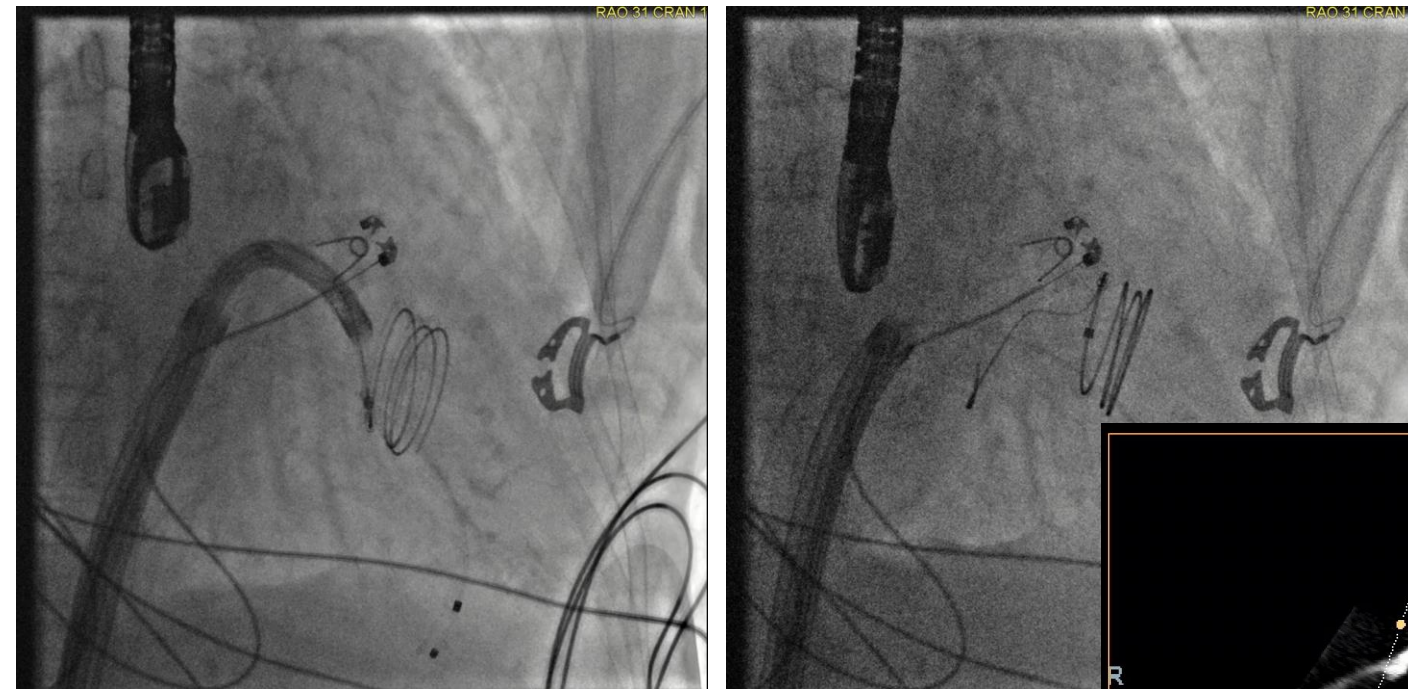


Third Encircling turn

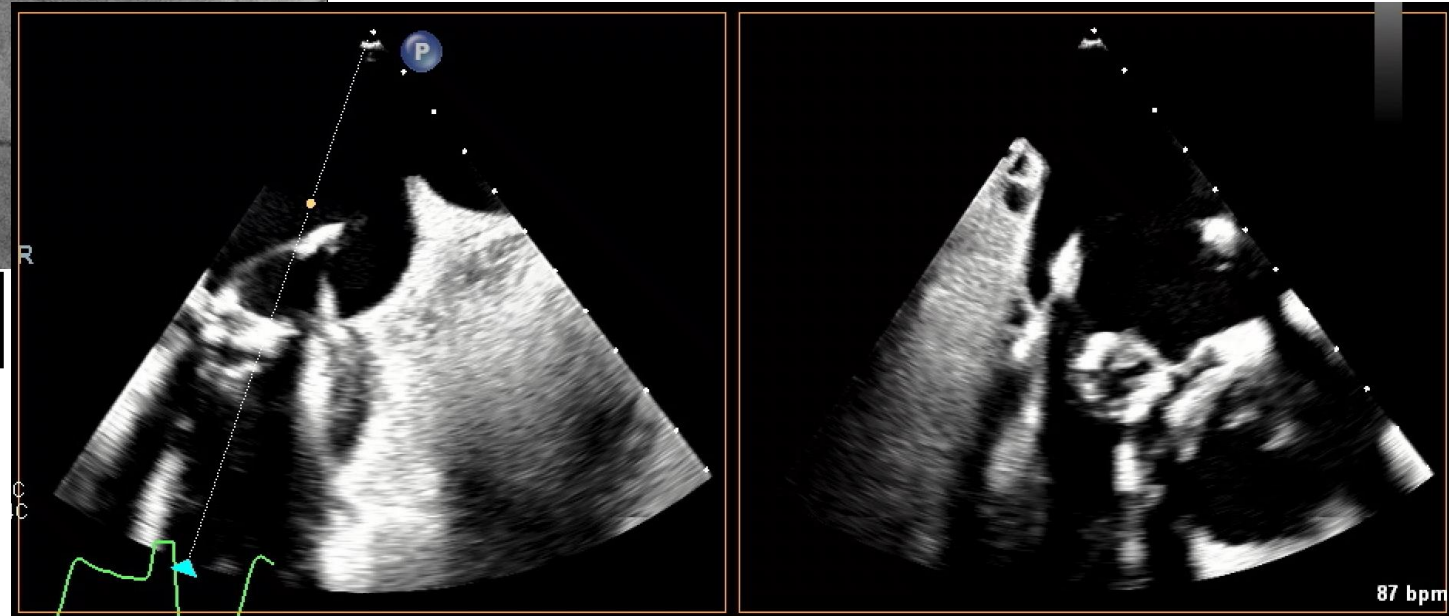


Caution: Investigational device. Limited by United States law to investigation use.

Sapien M3 Deployment



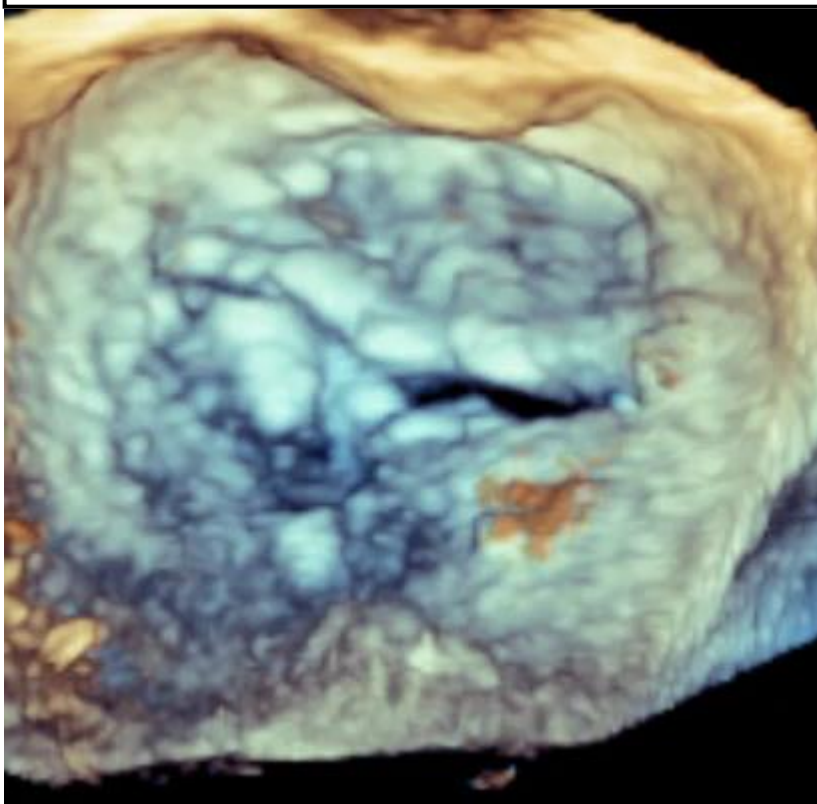
Revealing the atrial turn and deployment



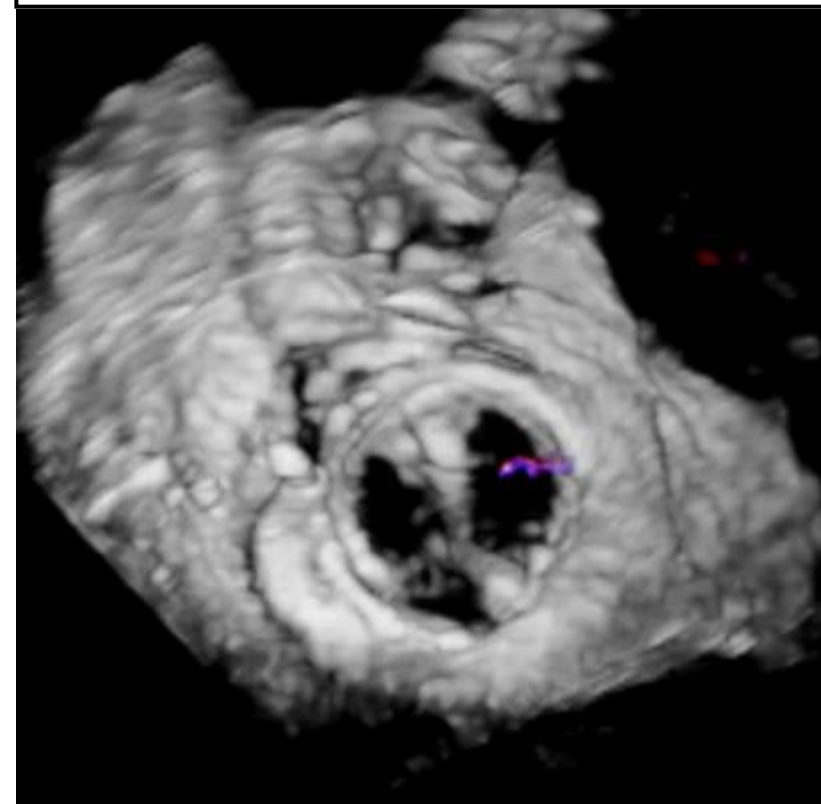
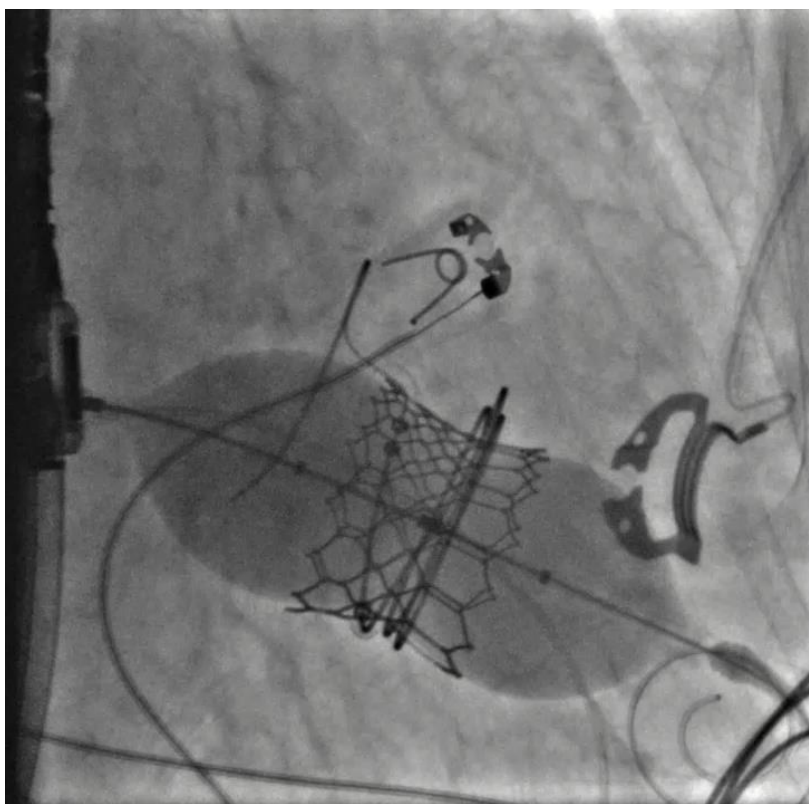
Caution: Investigational device. Limited by United States law to investigation use.

Final Result

Baseline

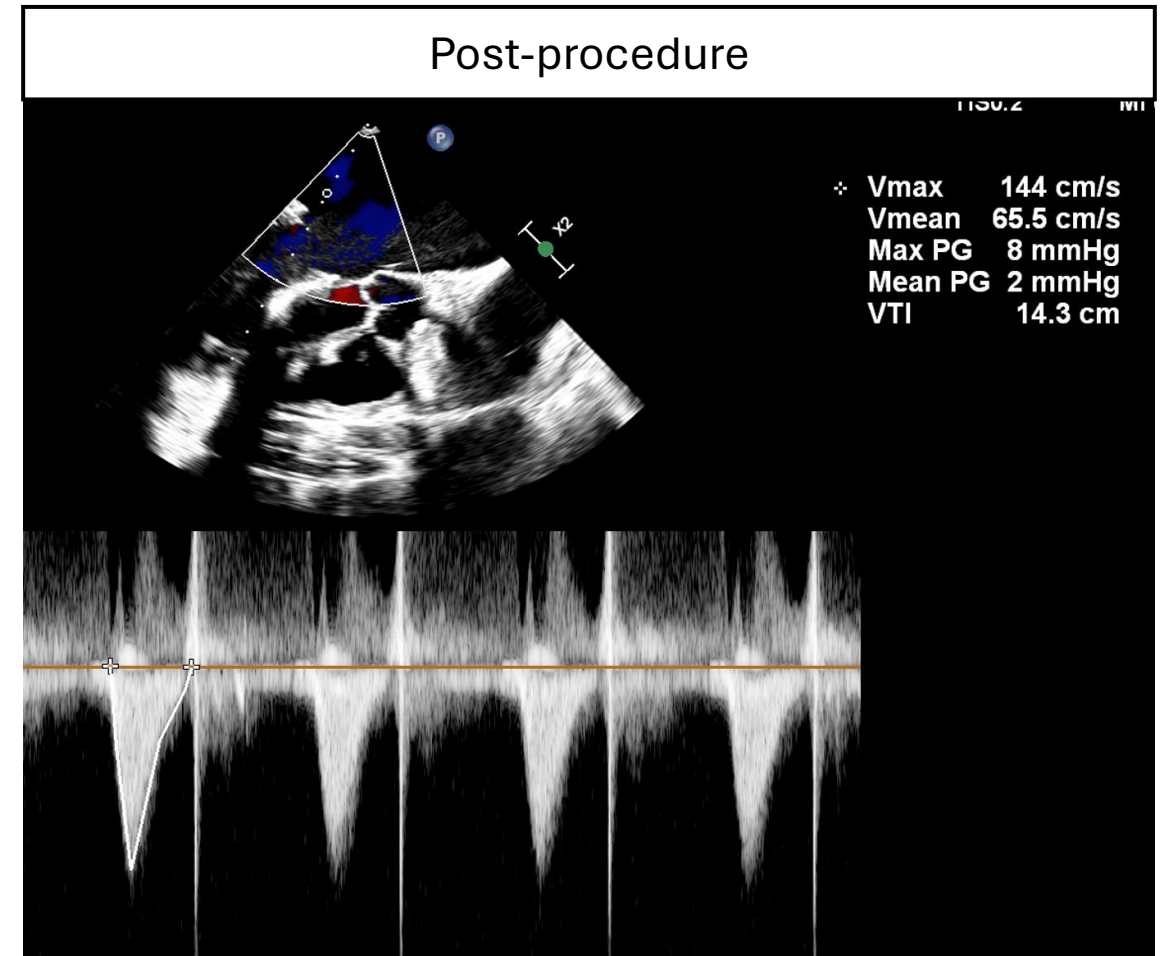
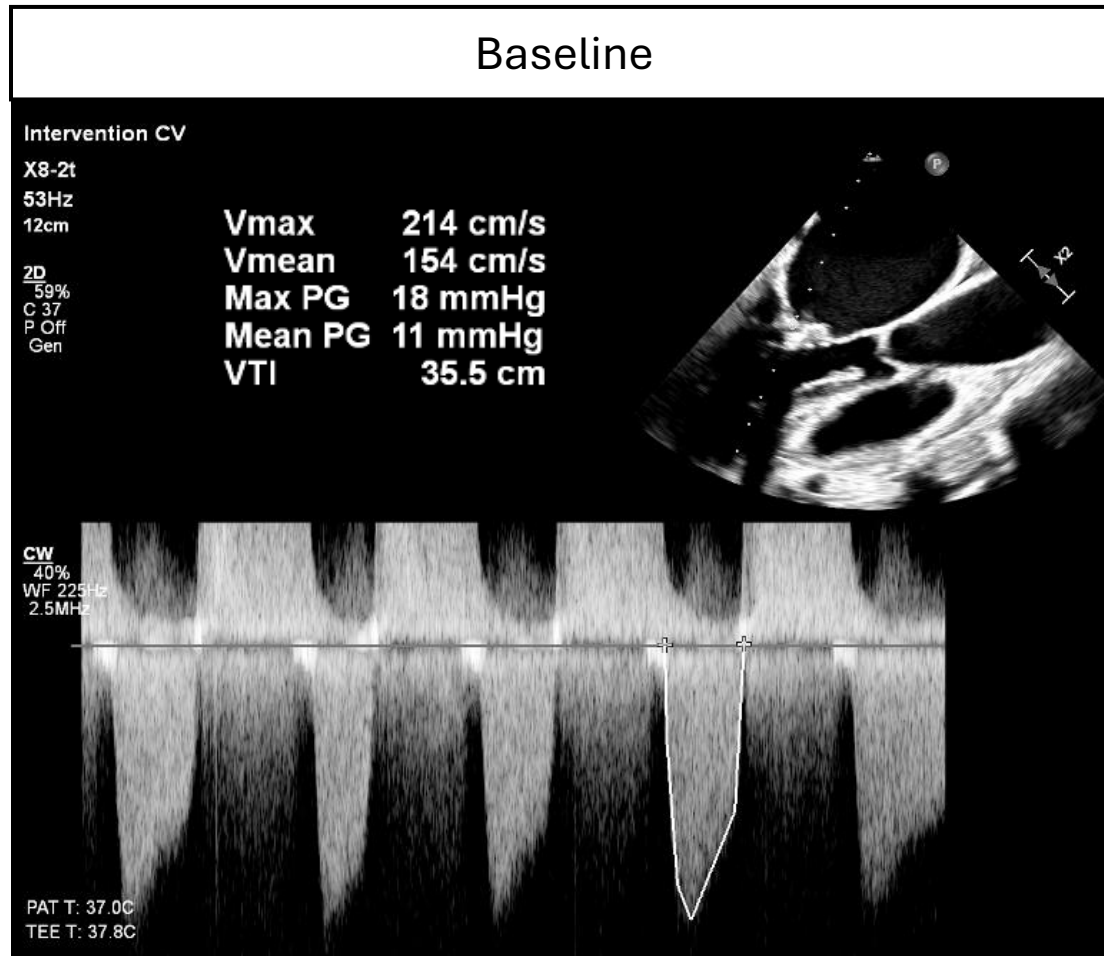


Post-procedure



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

Final Result



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



TAVR 2018

Mitral ViV
2024

Tricuspid clip 2019
&
Evoque 2024

NOTE: The information, procedural techniques and approaches, content, considerations, and opinions expressed in this content and materials are those of the respective healthcare providers and do not necessarily reflect the opinions, views, or training requirements of Edwards Lifesciences. This content and materials are intended to be an educational resource and for general information only. These content and materials are not intended to replace product training. These materials and content do not constitute medical or business advice or in any way replace the independent medical judgment of a licensed and trained physician with respect to any patient, their needs, or their circumstances. The physician is solely responsible for all decisions and medical judgments relating to the treatment of the patient. Please see the current complete Instructions for Use for products discussed or demonstrated, including all product indications, contraindications, precautions, warnings, and adverse events. The materials are prepared by trained healthcare professionals, who have been using the products or procedures they discuss regularly within their practices, and the use and outcomes may vary.

PP--US-11797 v1.0