APOLLO TMVR Trial Update: Case Presentation

Anelechi Anyanwu, MD, MSc, FRCS-CTh

Professor and Vice-Chairman
Department of Cardiovascular Surgery
Icahn School of Medicine at Mount Sinai
New York, NY

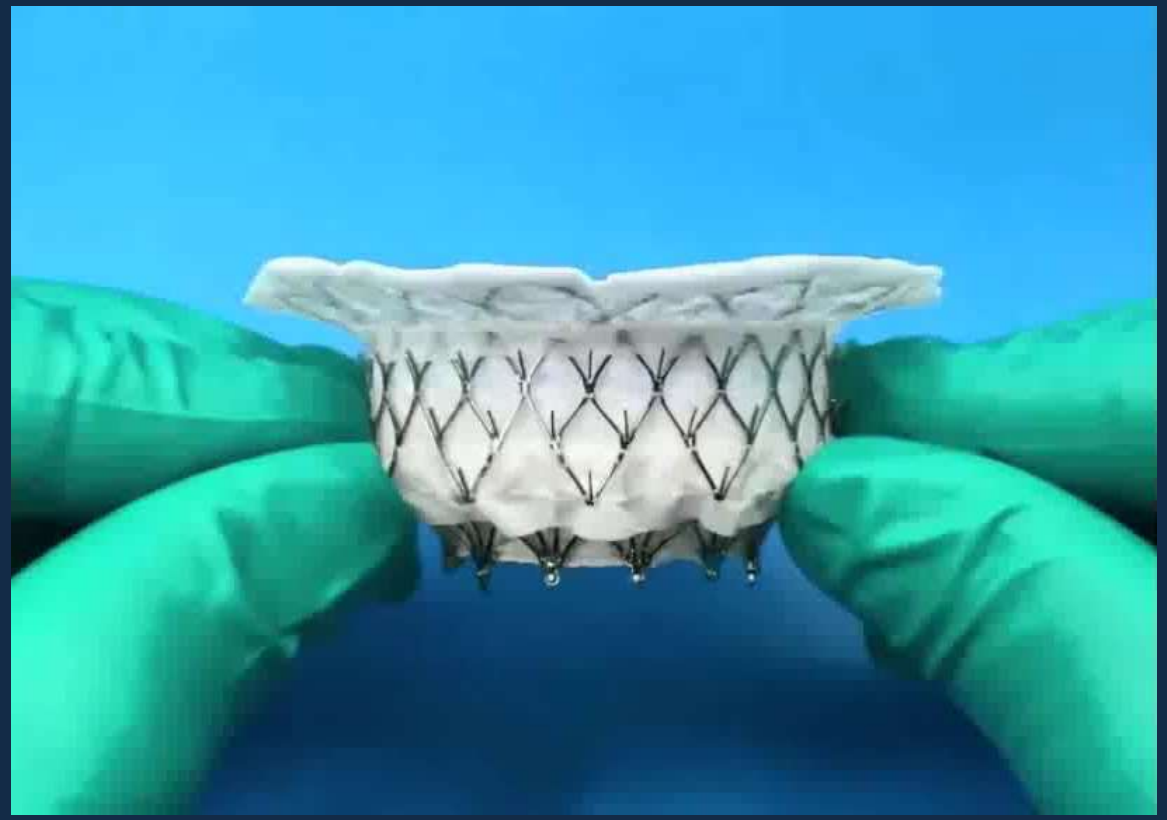
Mount Sinai

MITRAL FOUNDATION

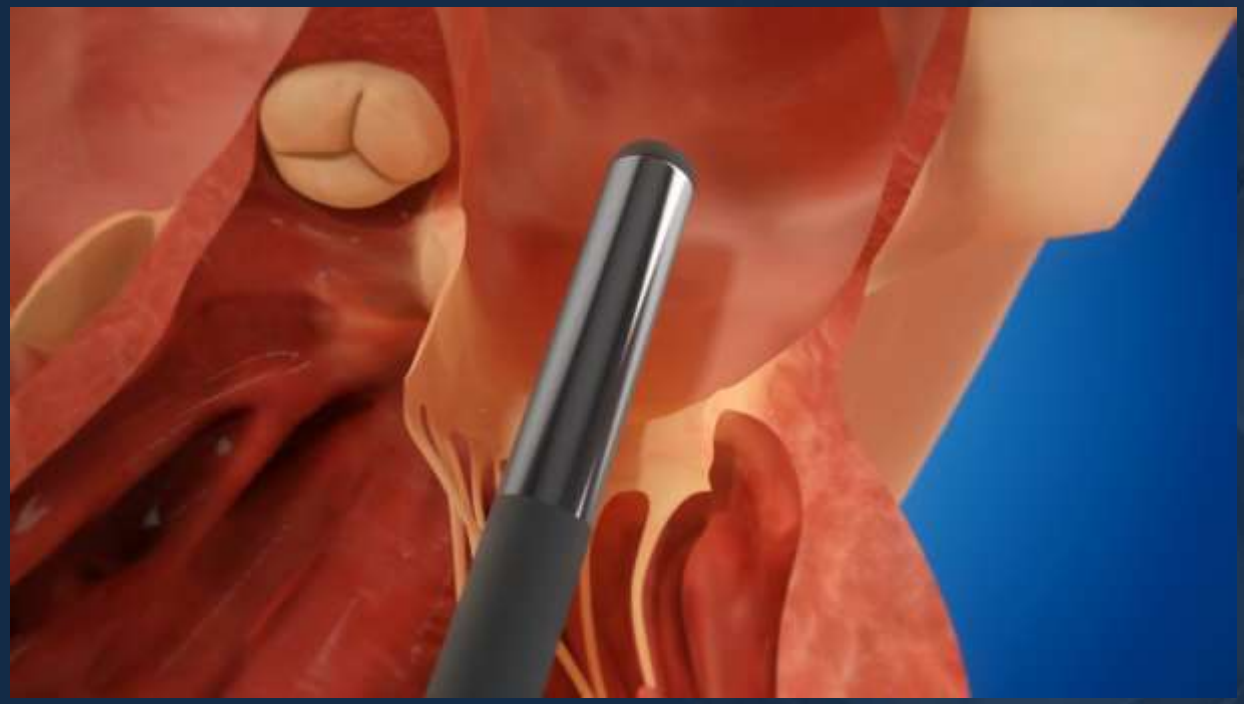
Disclosure

- I will discuss use of an investigational device (Medtronic Intrepid TMVR)
- I have no financial disclosures

Medtronic Intrepid™ TMVR



Self expanding nitinol valve
27mm tri-leaflet bovine pericardium valve
43, 46 or 50 mm diameter



Transapical Delivery (35 F Sheath)

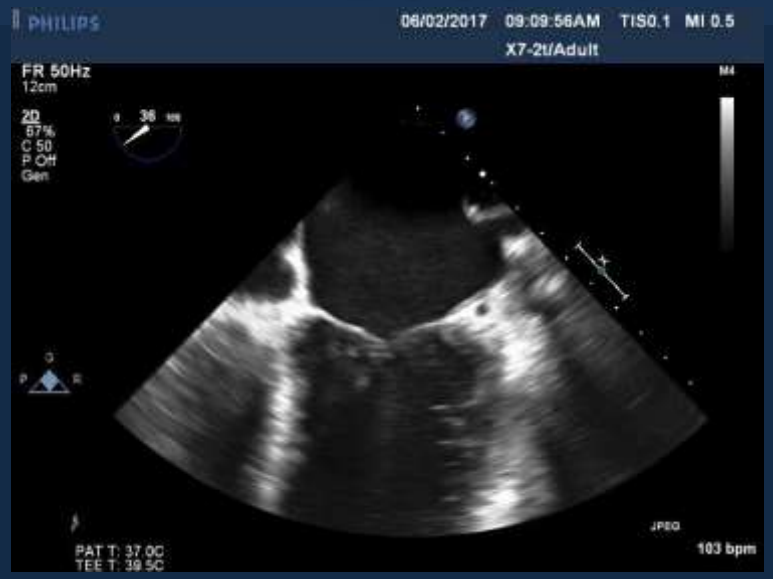
CAUTION: Investigational Device Limited by Federal (United States) Law to Investigational Use. Medtronic Animation

Case Presentation

- 77-year-old female dyspnea on minimal exertion
- Two prior sternotomies CABG (2005), AVR (biological) (2013)
- Ischemic cardiomyopathy (LVEF 27%, AICD)
- Multiple hospitalizations for CHF exacerbations

- Other comorbidity - CKD, PVD (toe amputation), TIA, AF
- STS Score (MV repair) 9.21

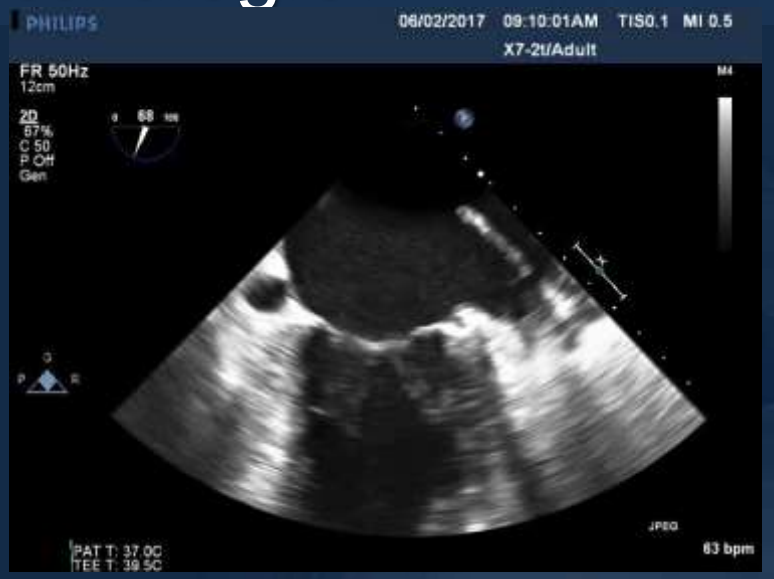
Baseline Transesophageal Echocardiogram

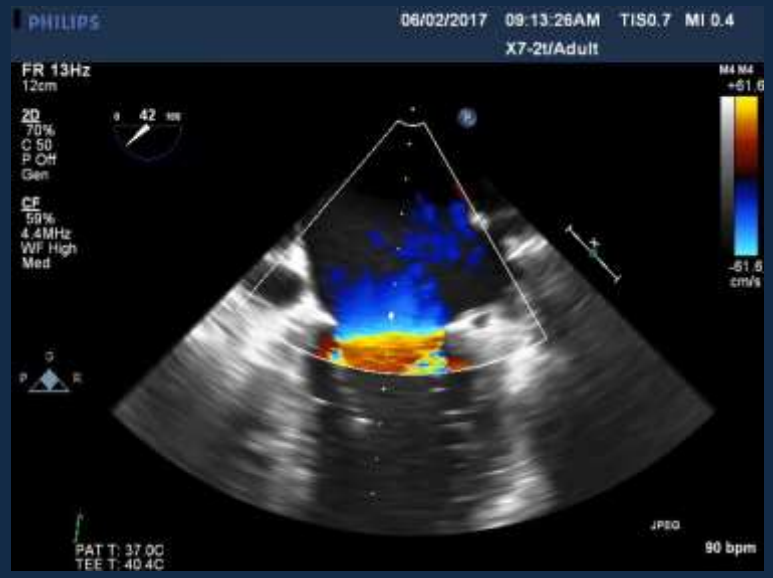


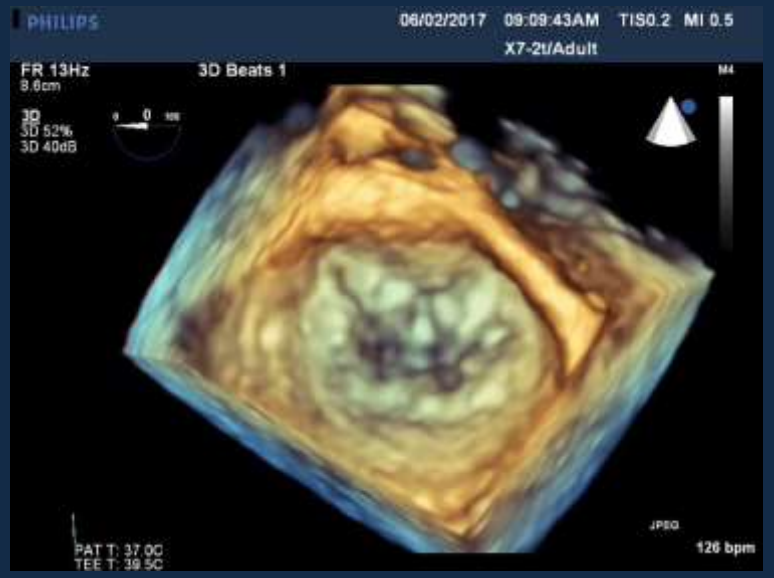
BP 106/53 Height 5ft 4in

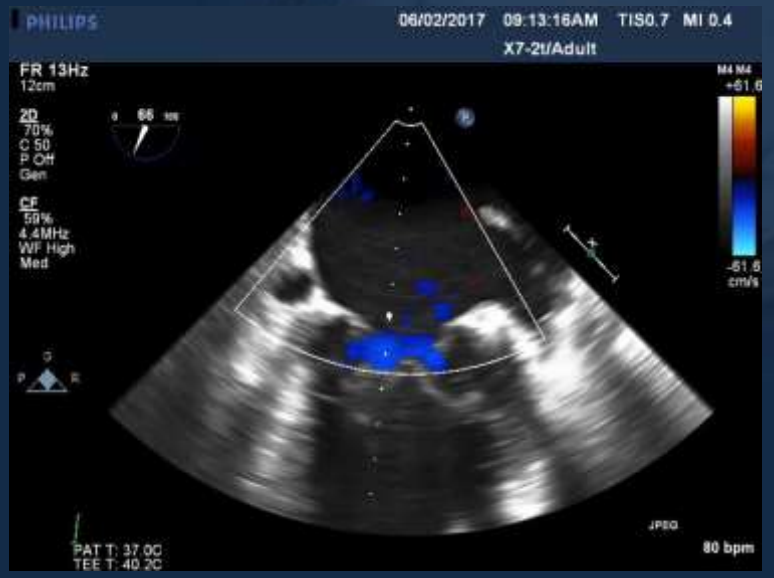
Weight 173lb

LVEF 26%



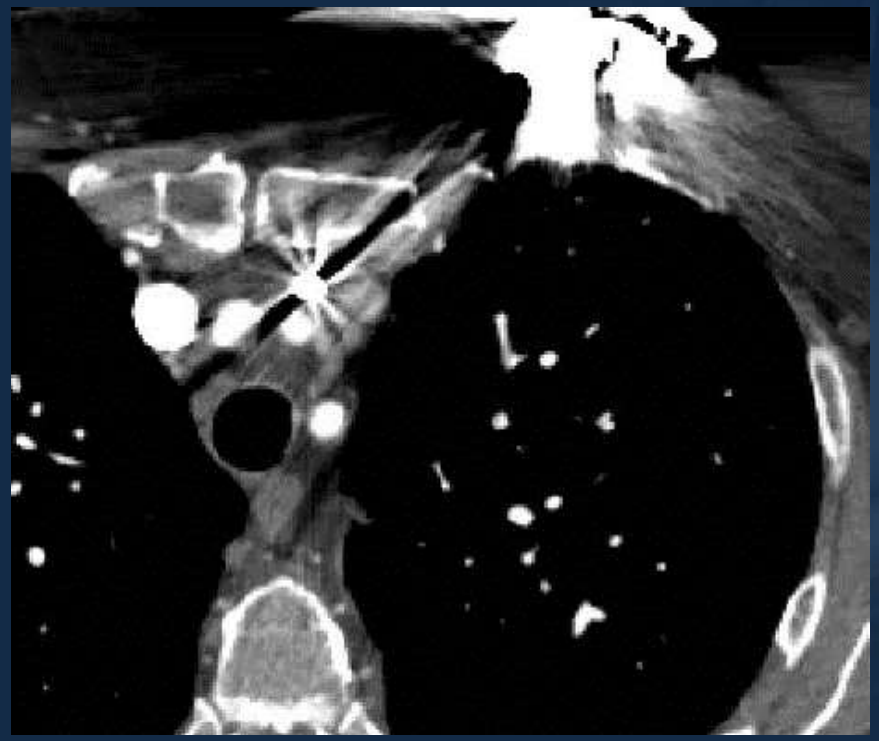






Further Work-up

- RHC: PCW 34/45 mmHg, PA 64/25/38mmHg, RA 60/14mmHg, CO 4.3L/min
- CTA:
  - Patent SVG's (LAD, RCA)
  - LVEF 26%
  - Focal ascending aorta calcification,
  - Celiac artery occlusion (SMA collaterals)

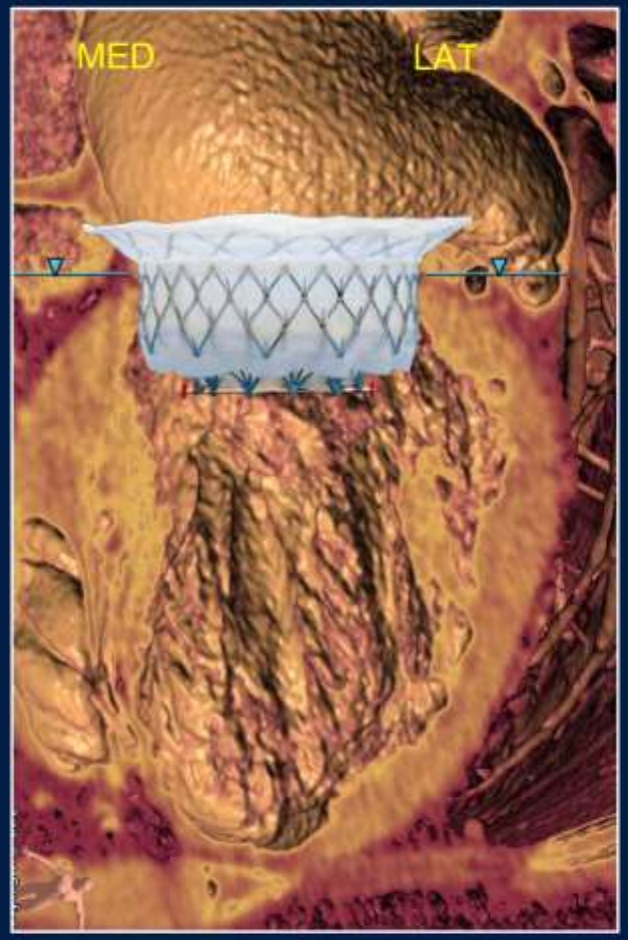


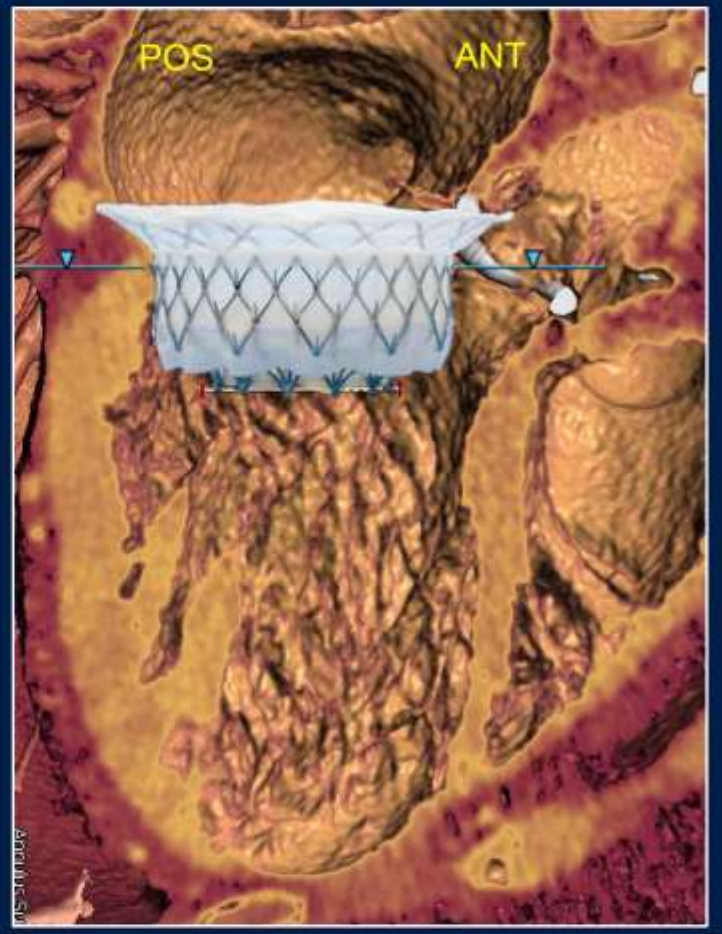
Heart Team Review

- Declined for surgery due to prohibitive risk
- Enrolled in the Intrepid Global Pilot Study

SURGICAL PLANNING
ANNULUS SIZING

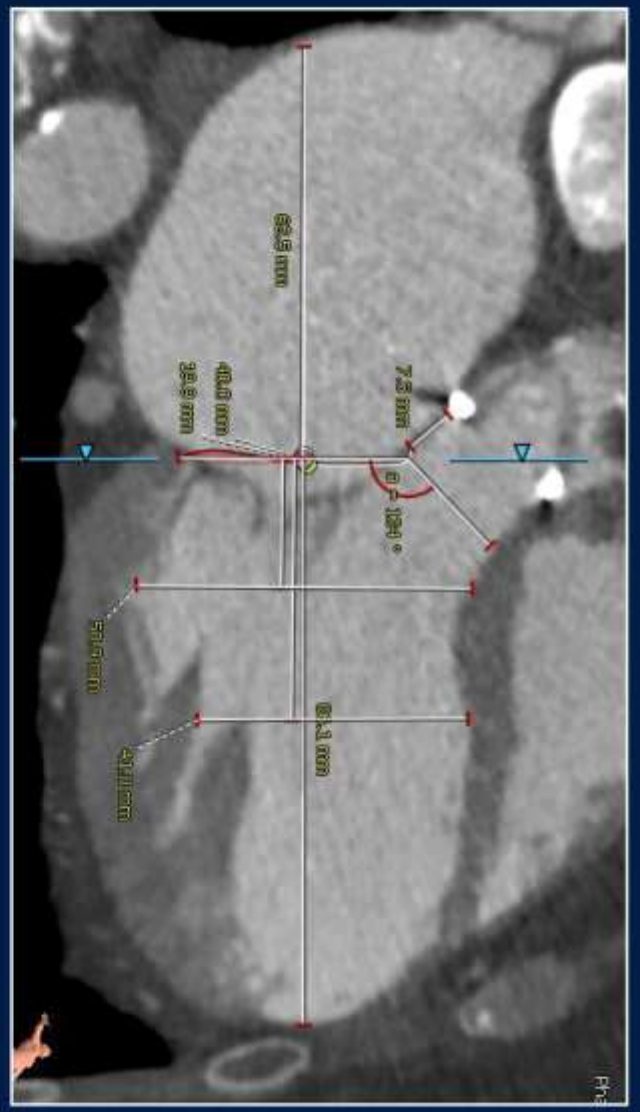
- 43mm implant
- 15% perimeter oversizing
- 20% diameter oversizing
- 17% CC compression
- Patent LVOT





SURGICAL PLANNING
LVOT & LV ASSESSMENT

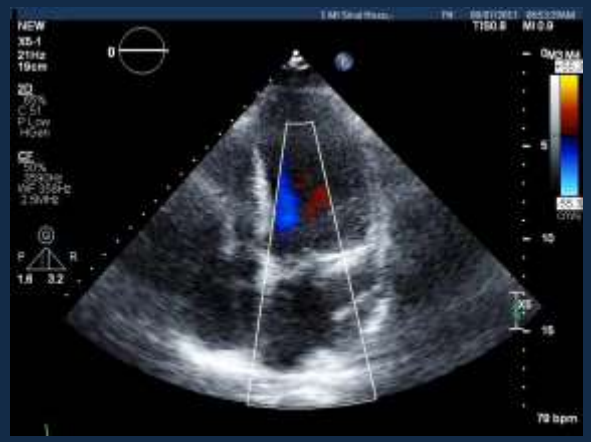
- Wide 135° aortomitral angle
- Very thin <1mm wall at incision site
- Similar thickness at diastole
- Anterior "annulus" 7.5mm from bioprosthetic Aortic Valve
- No interaction expected with AoV replacement

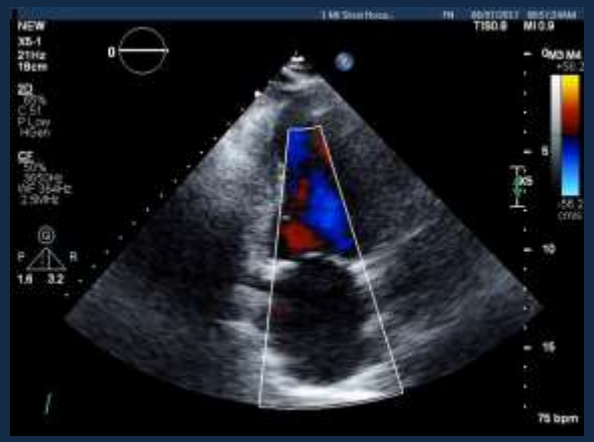


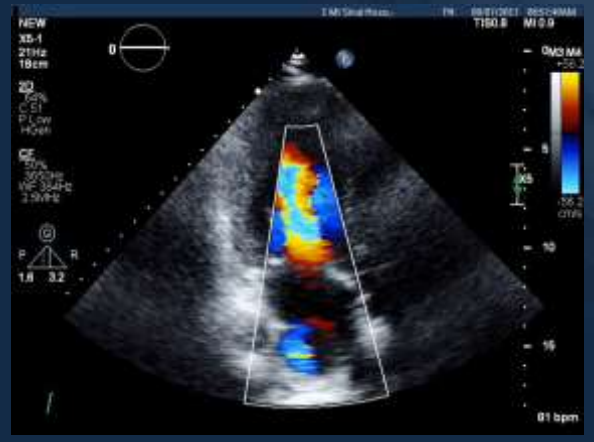
Medtronic

Preoperative Optimization – 3 Days prior to procedure

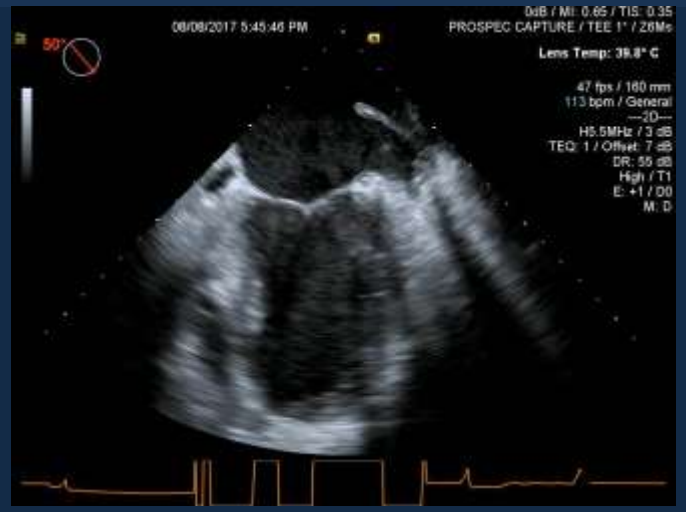
- Myocardial Contractility: Milrinone
- Diuresis: Intravenous Furosemide
- Nutrition
- Physical

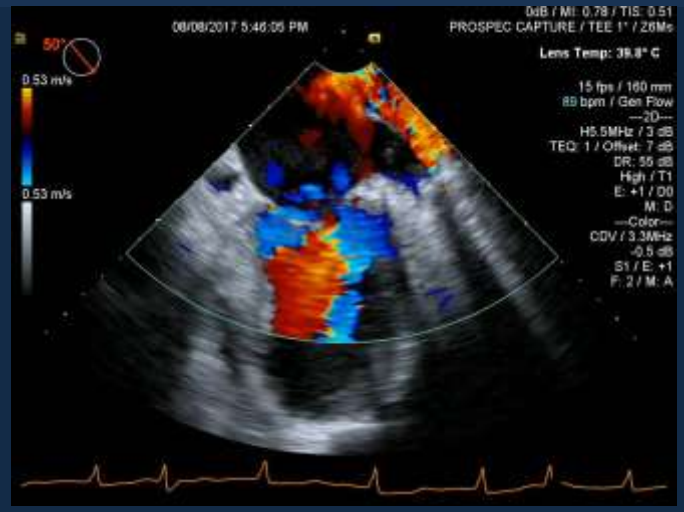




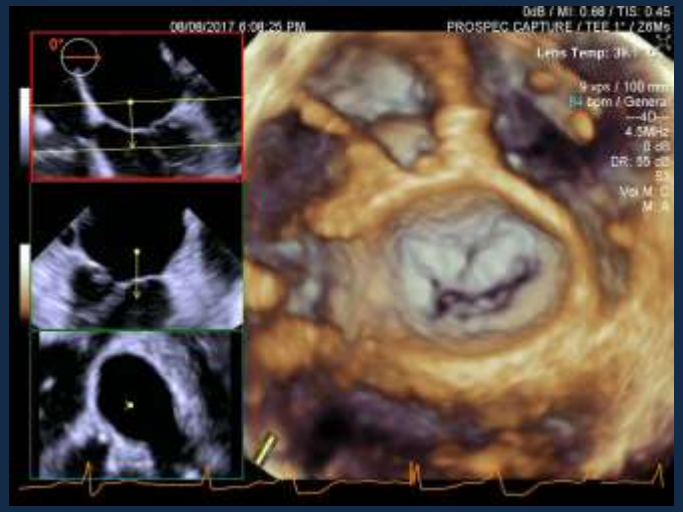


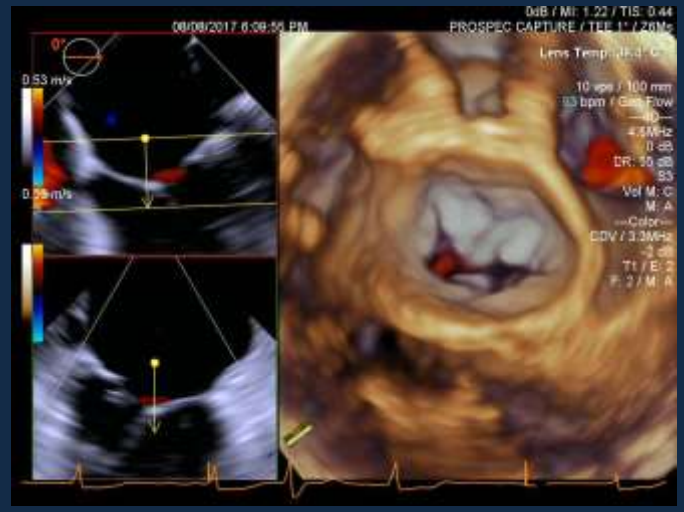
Procedure: Intrepid™ TMVR

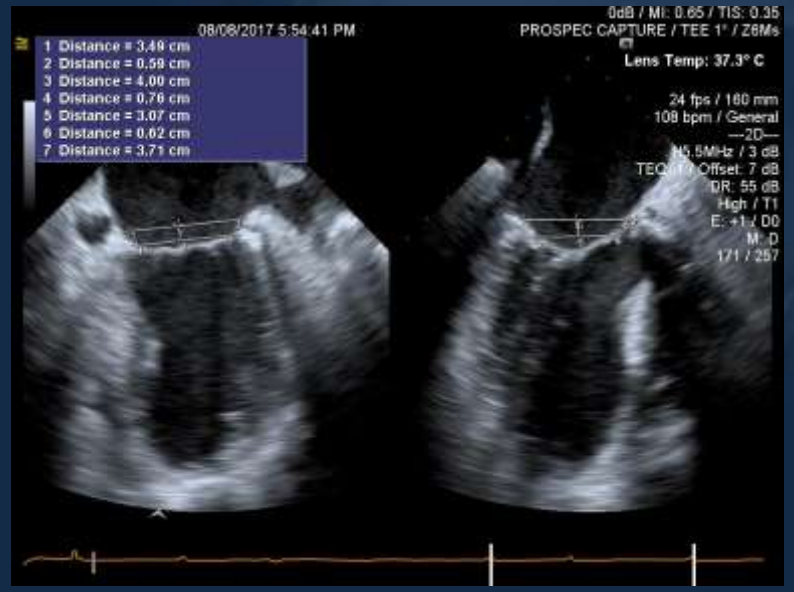




- Echo guided procedure
- Transapical surgical access

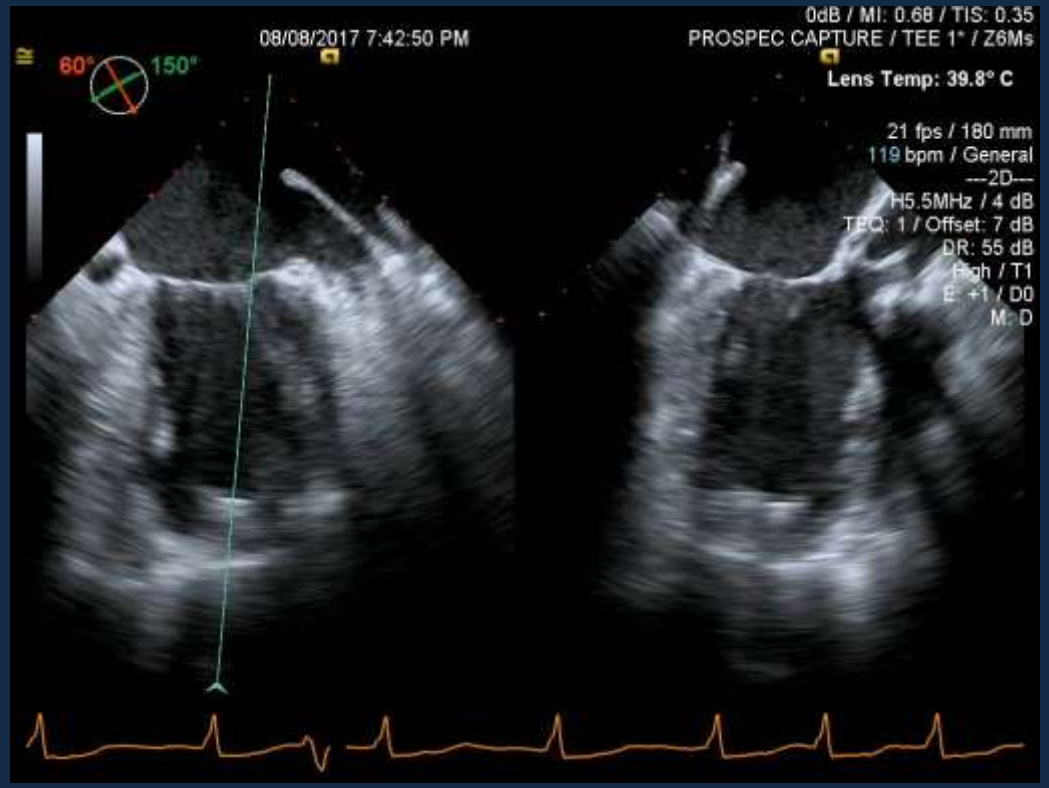


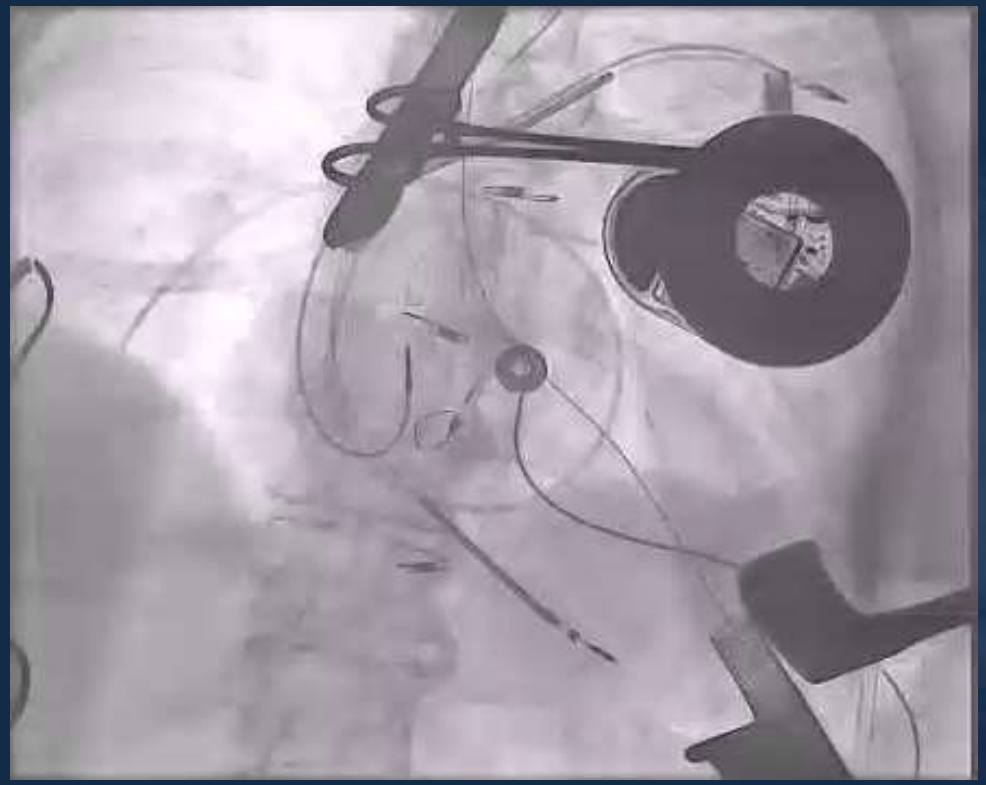




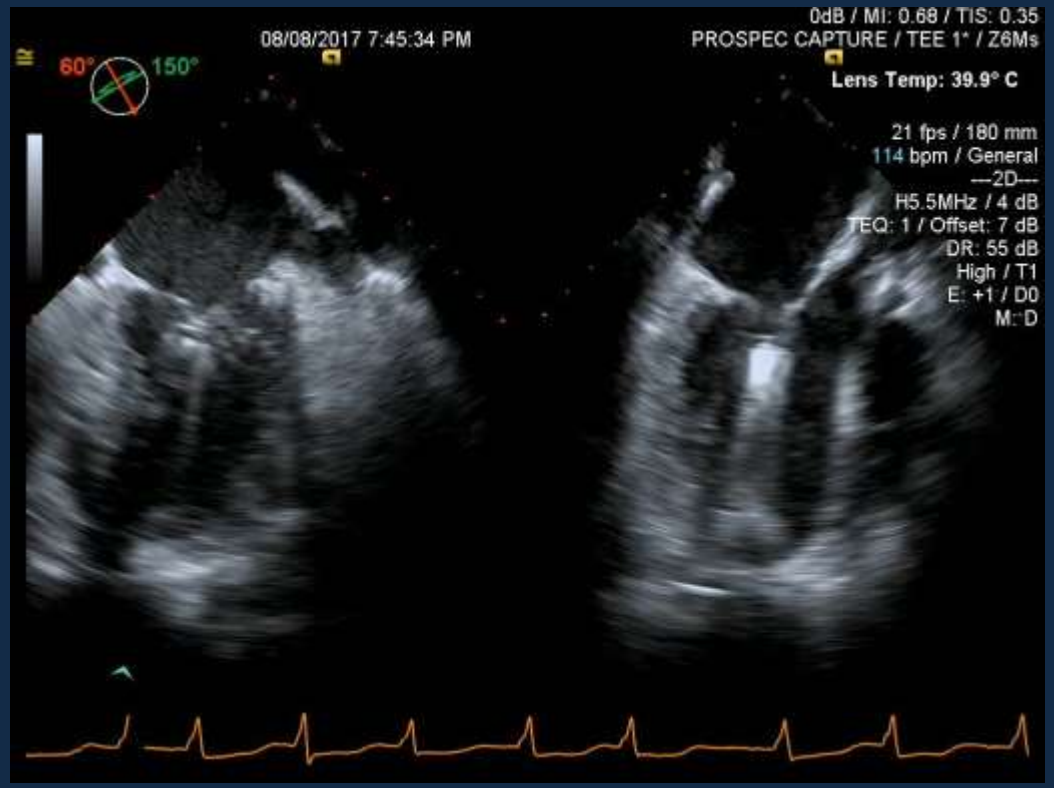
CAUTION: Investigational Device Limited by Federal (United States) Law to

Introducer Sheath Placed in Apex

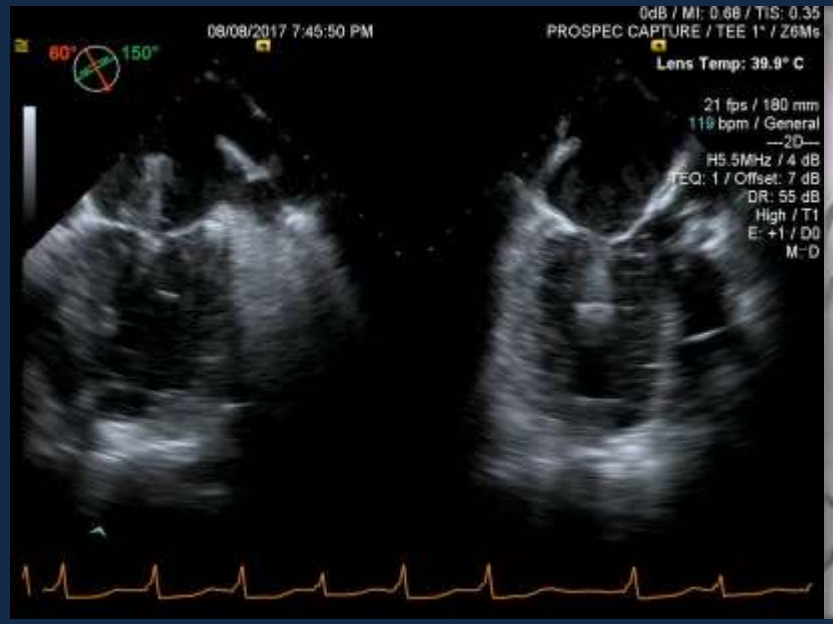


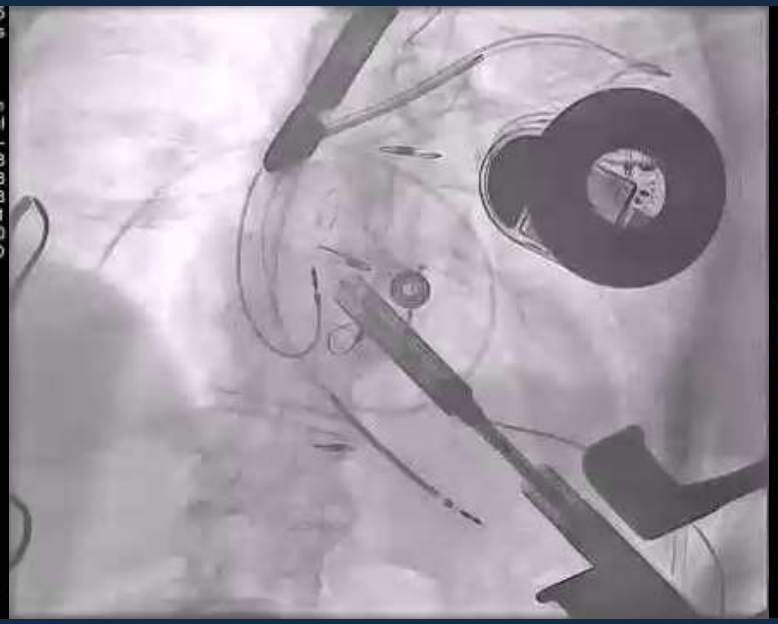


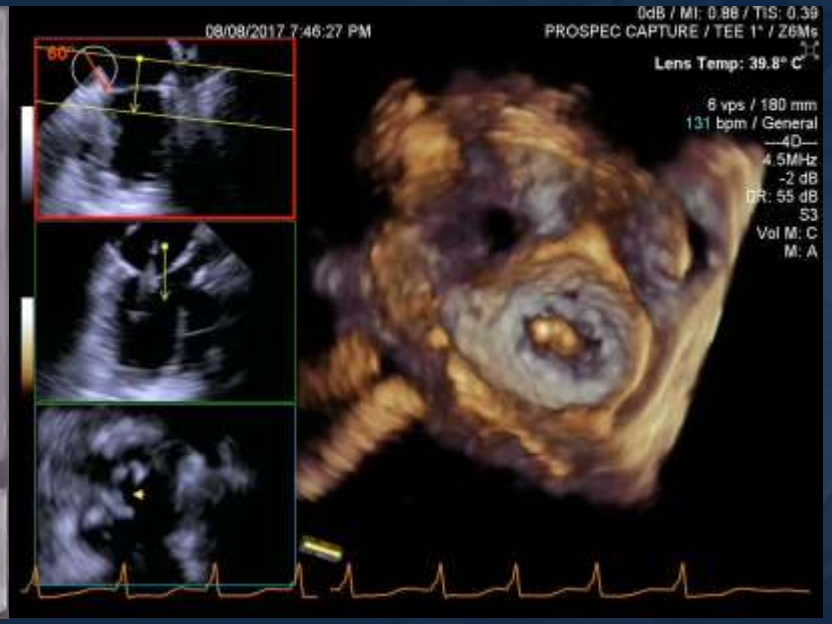
Catheter Advanced and Guided Through Mitral Valve



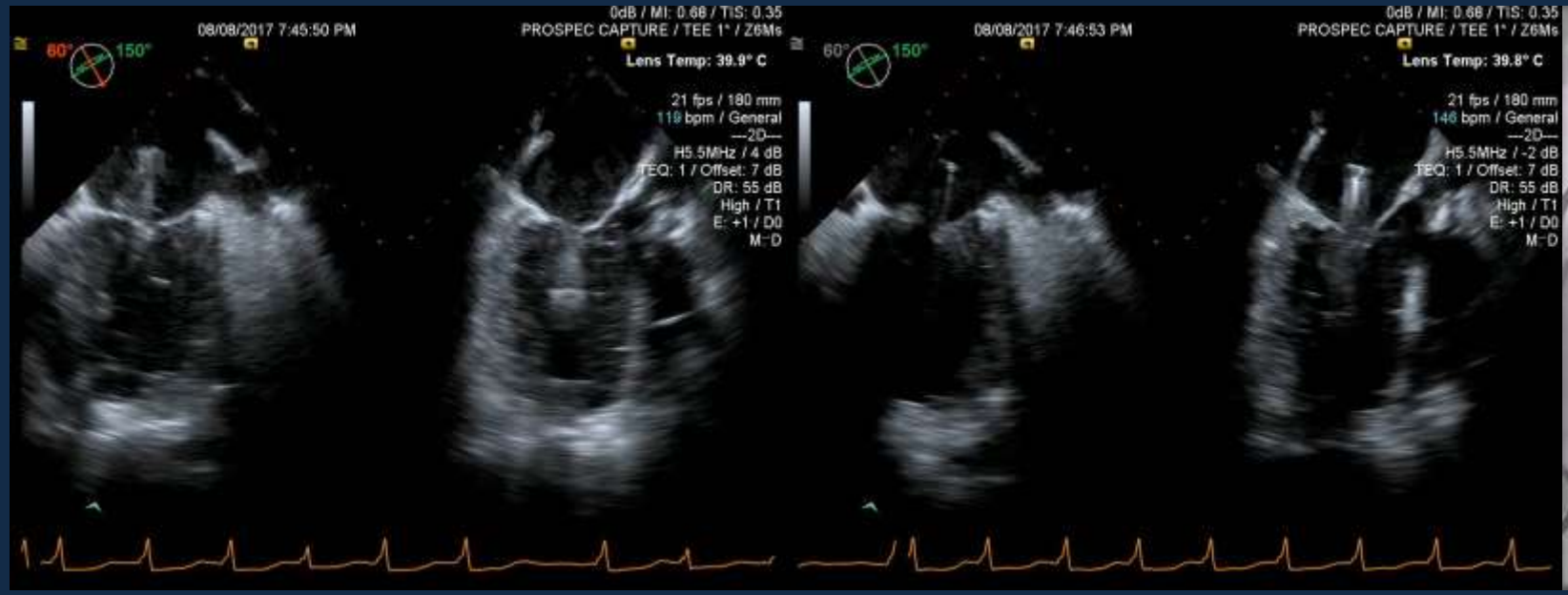
Catheter in Left Atrium



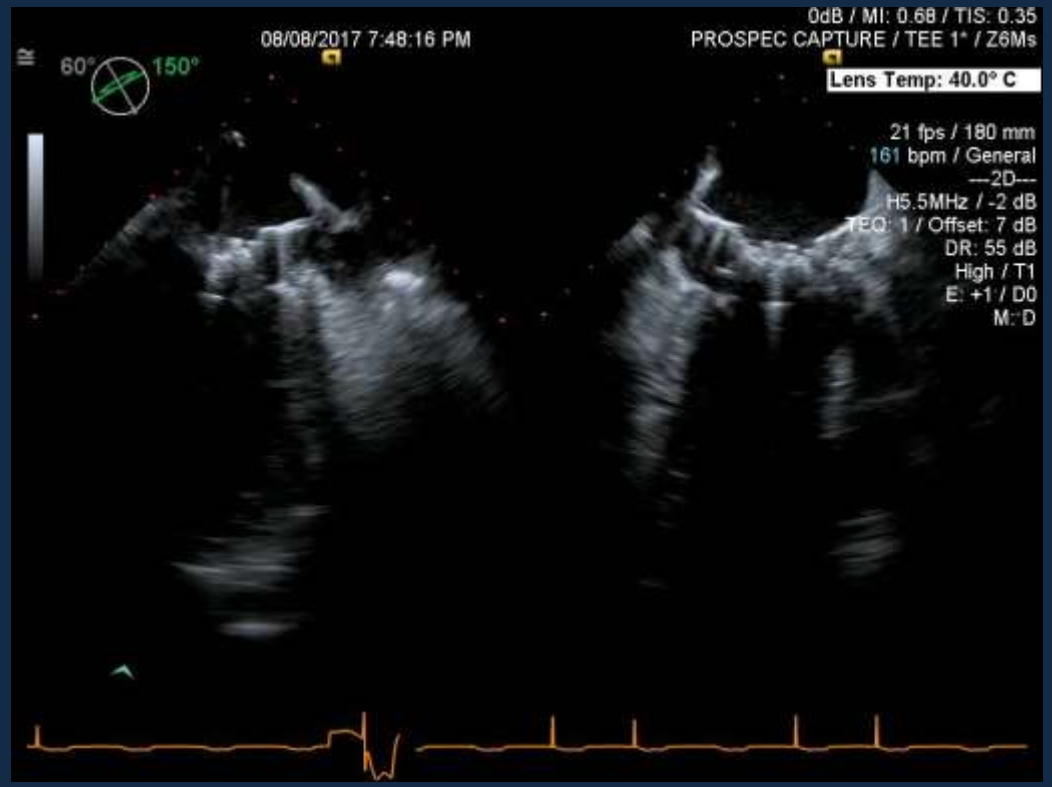


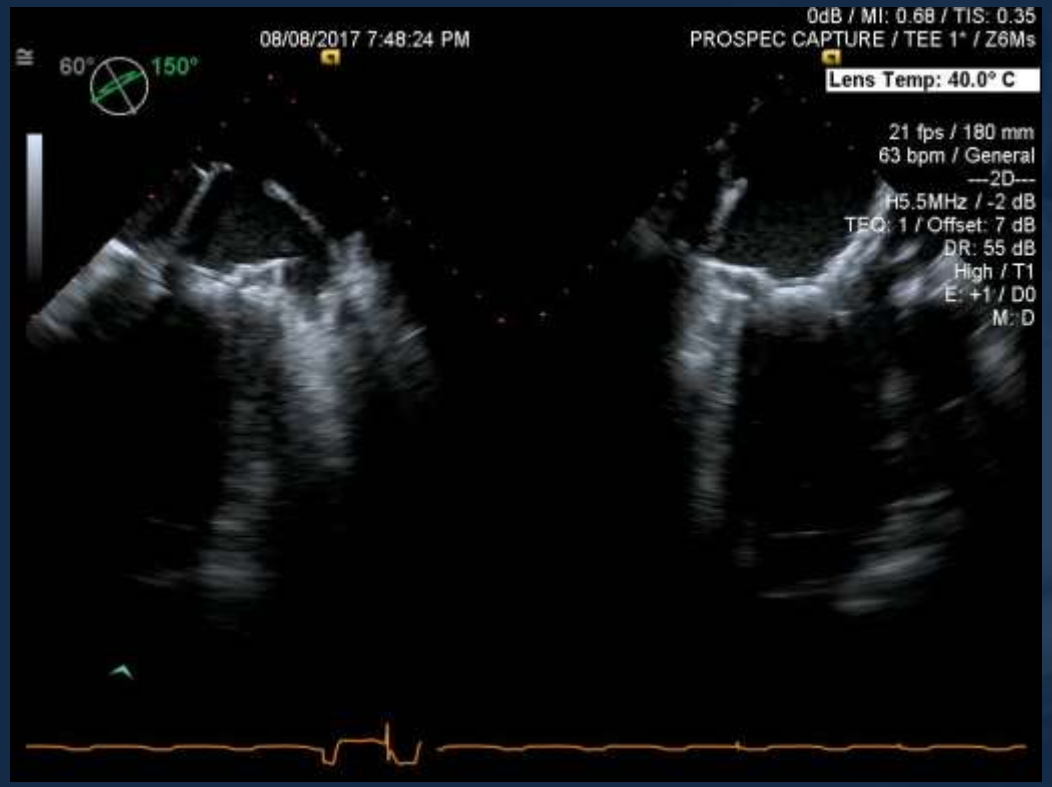


Partial Device Release and Alignment with Annulus

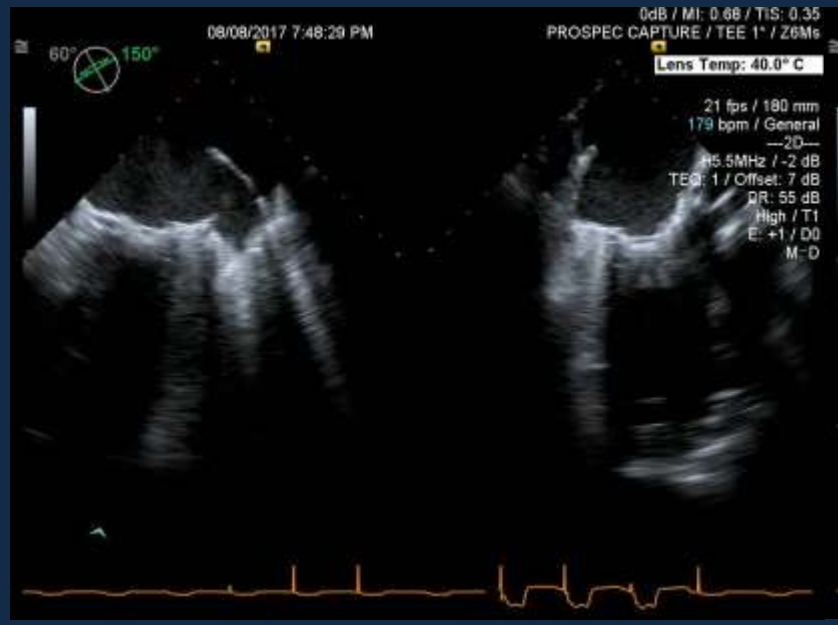


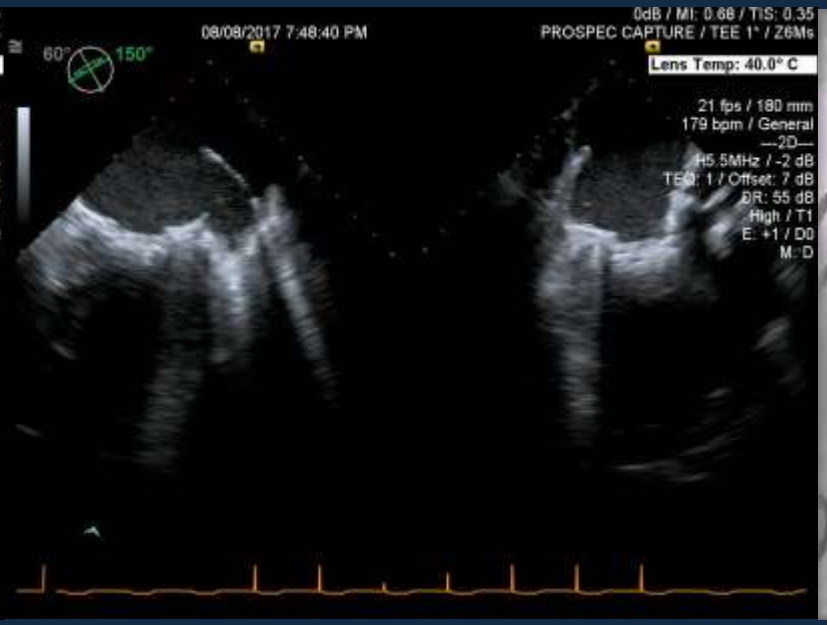
Rapid Pacing & Implant Positioning Parallel to Mitral Plane

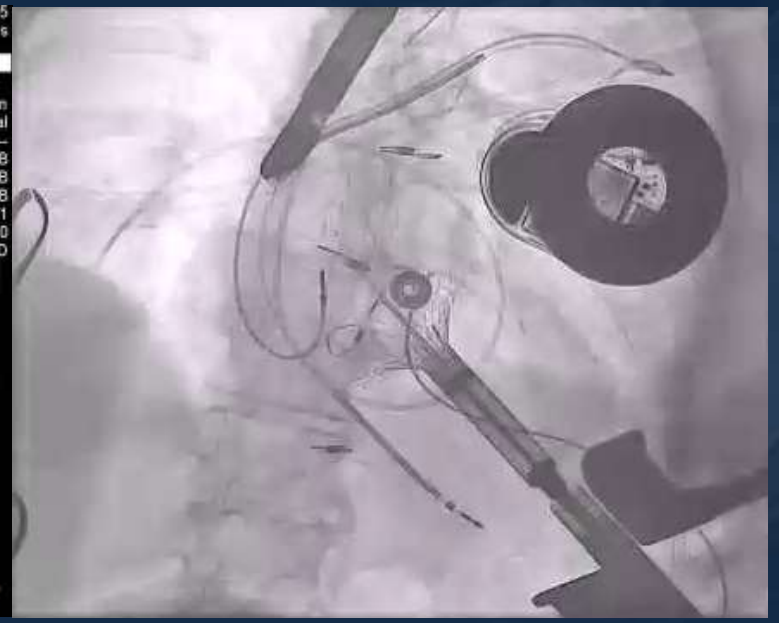




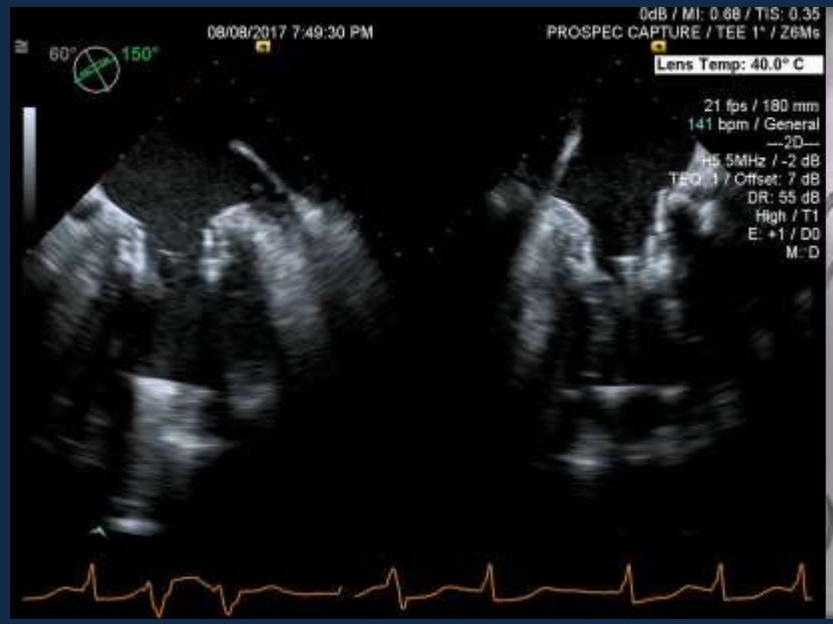
Rapid Pacing, Retraction of Device & Valve Deployment

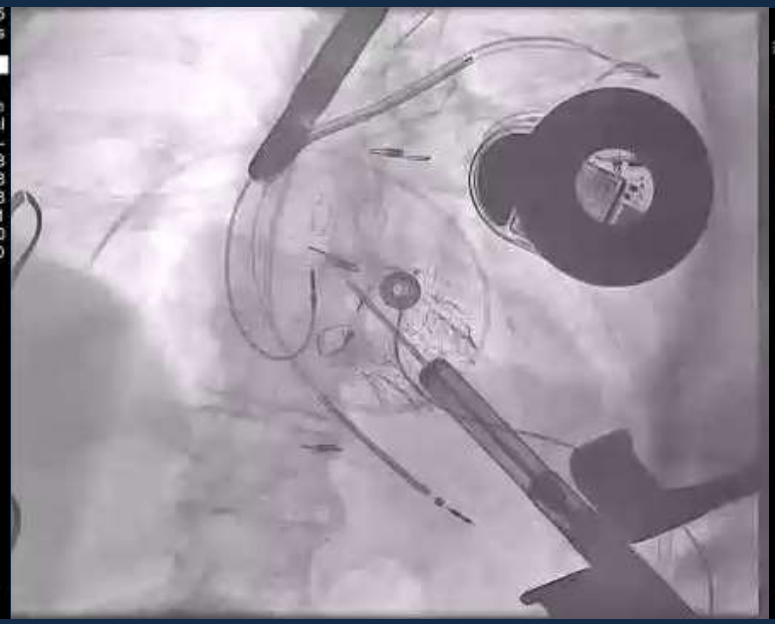


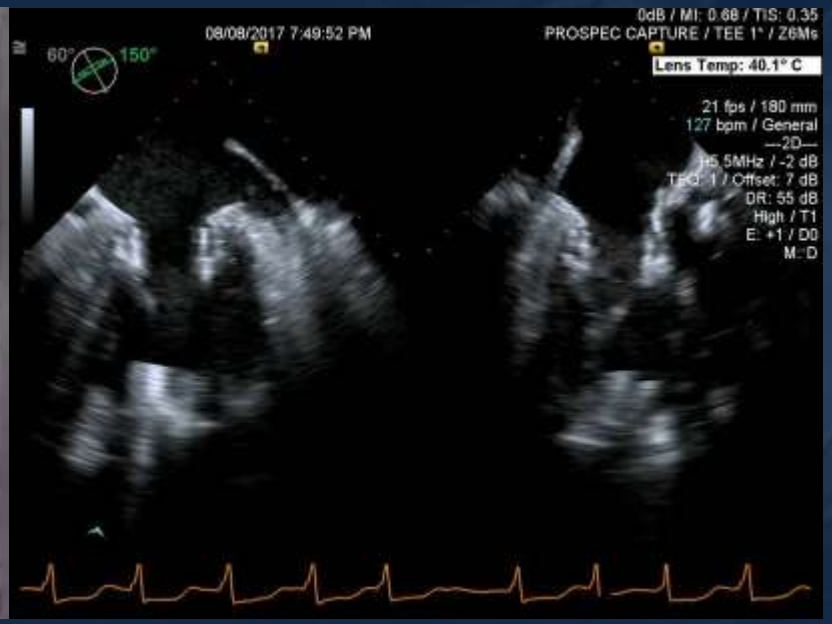




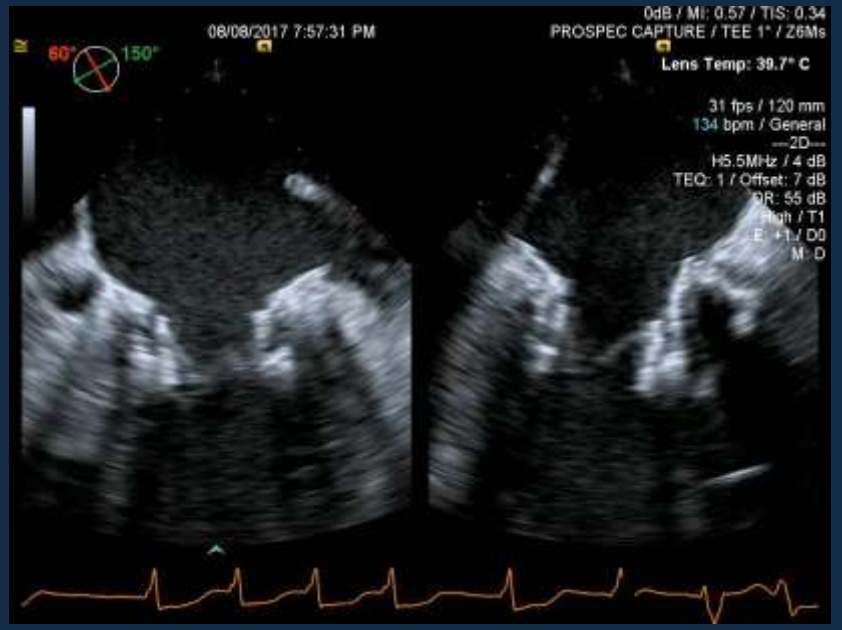
Final Deployment Complete and Delivery Catheter Withdrawal

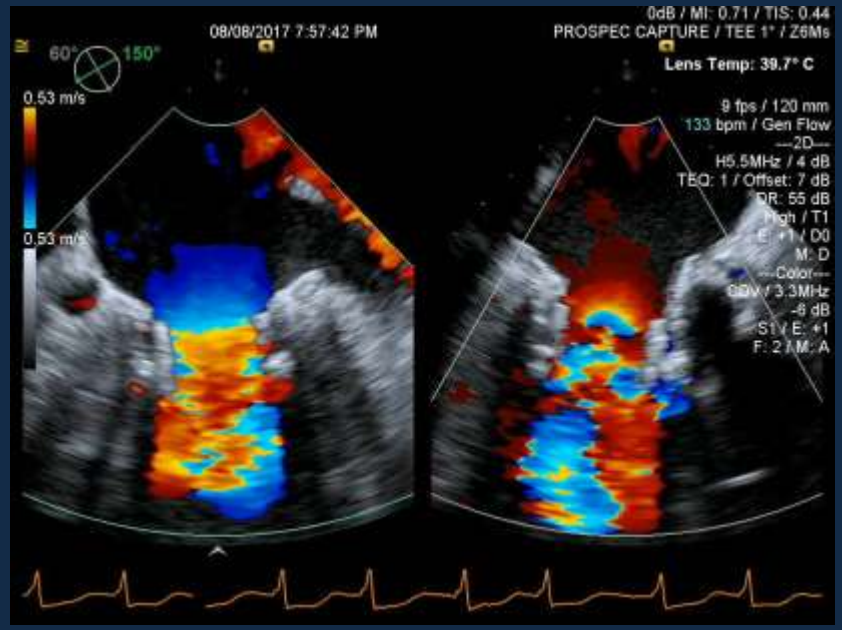


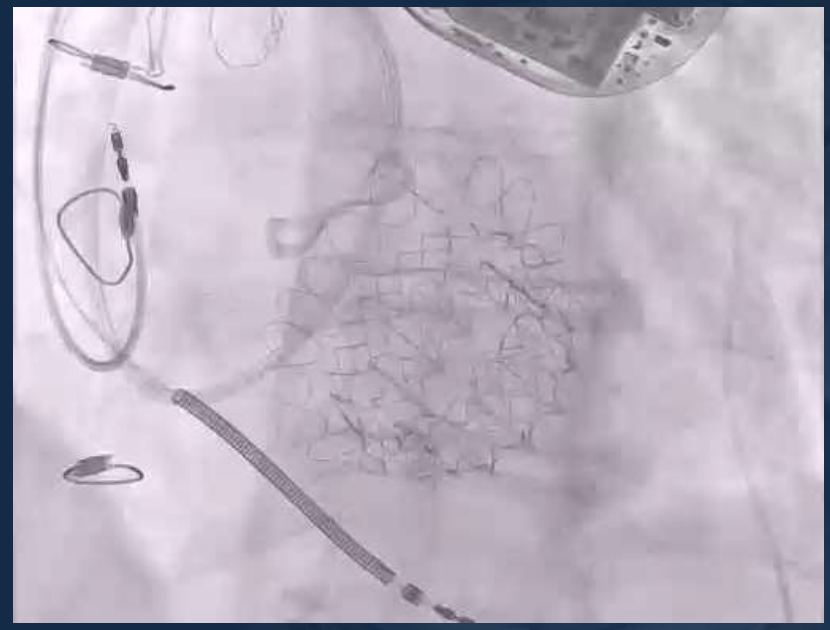




Final Result

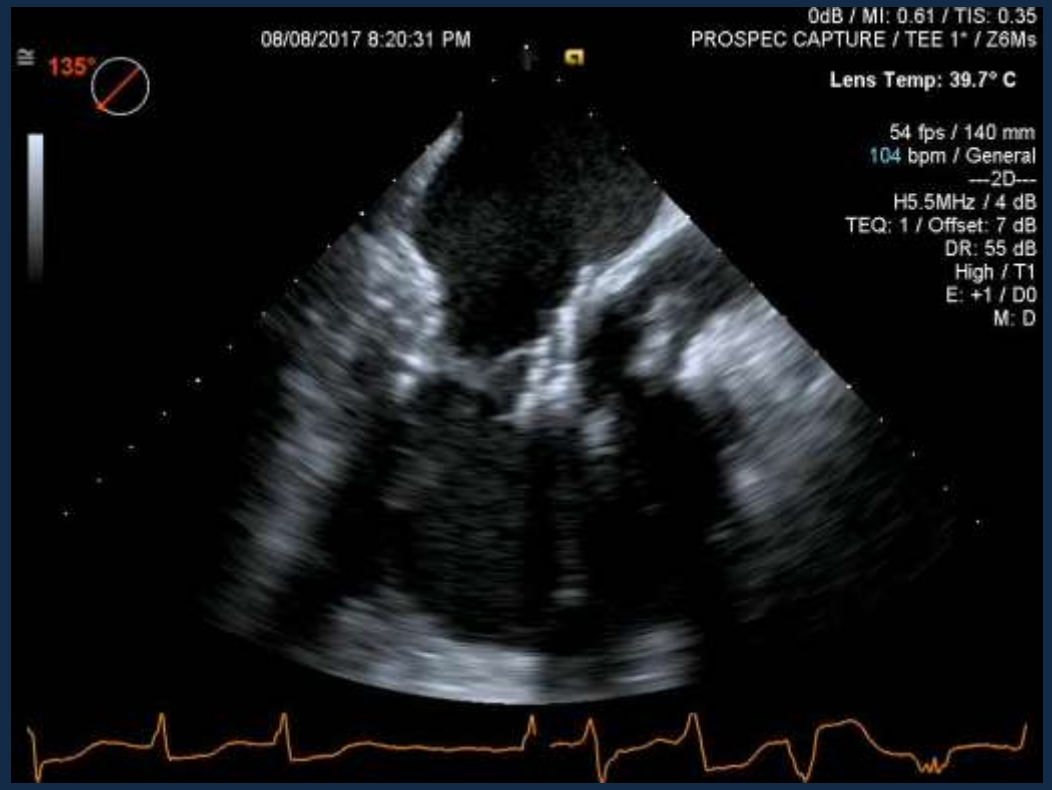


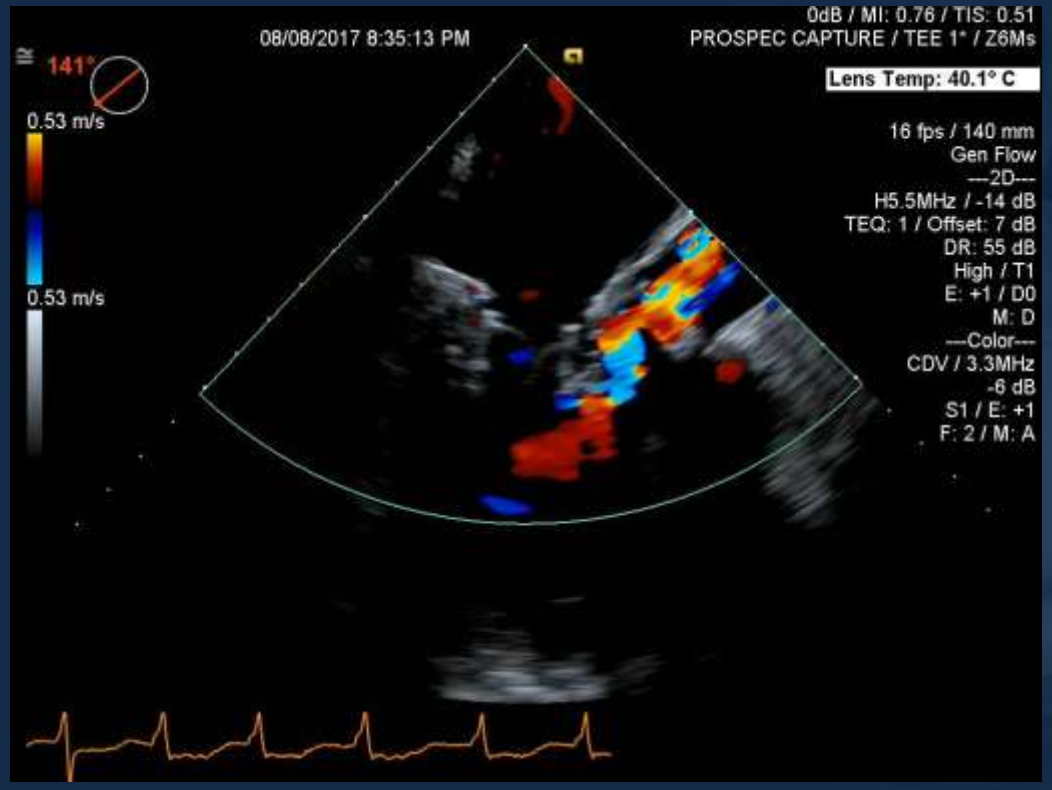




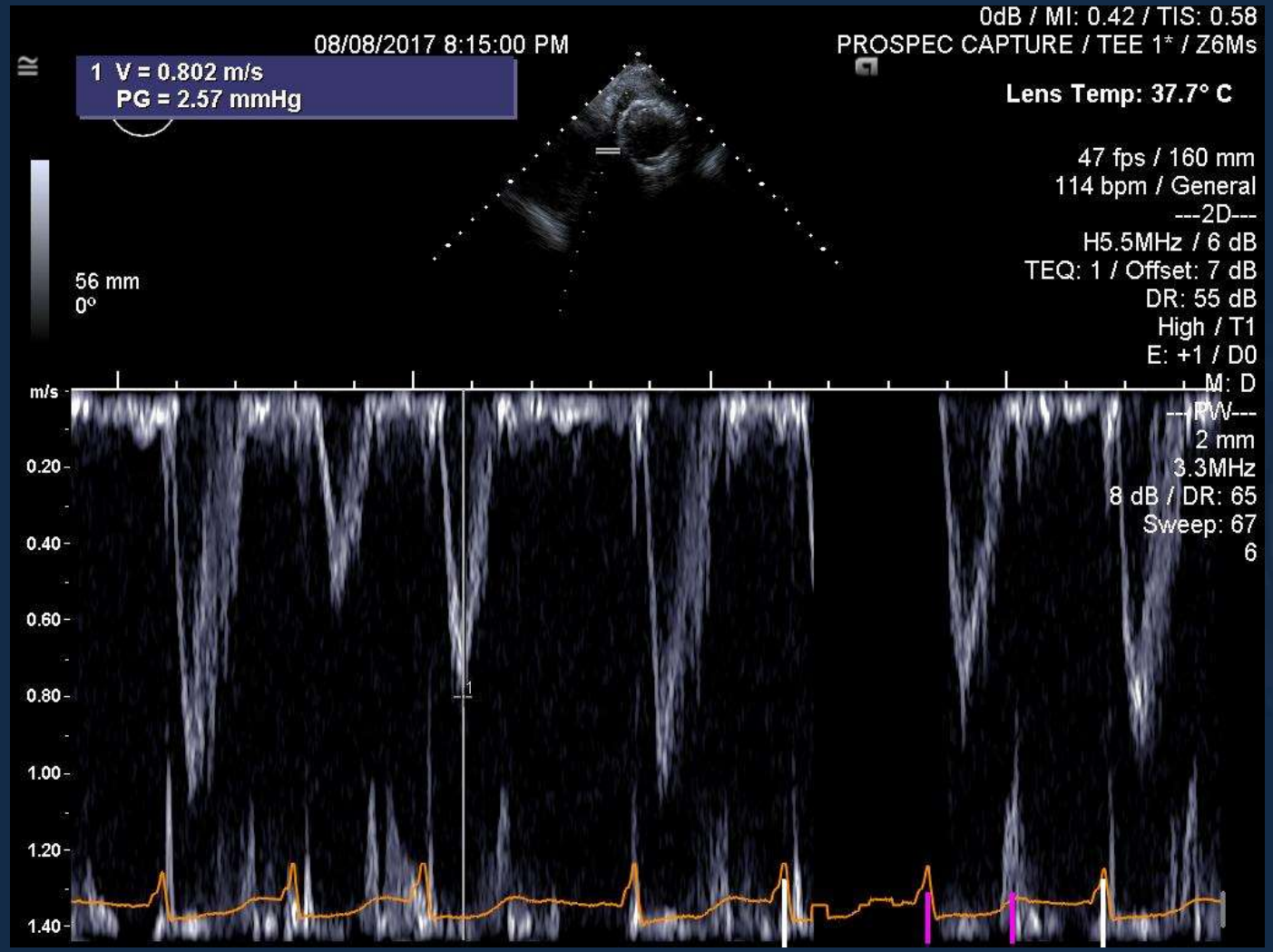
CAUTION: Investigational Device Limited by Federal (United States) Law to Investigational Use

Final Result



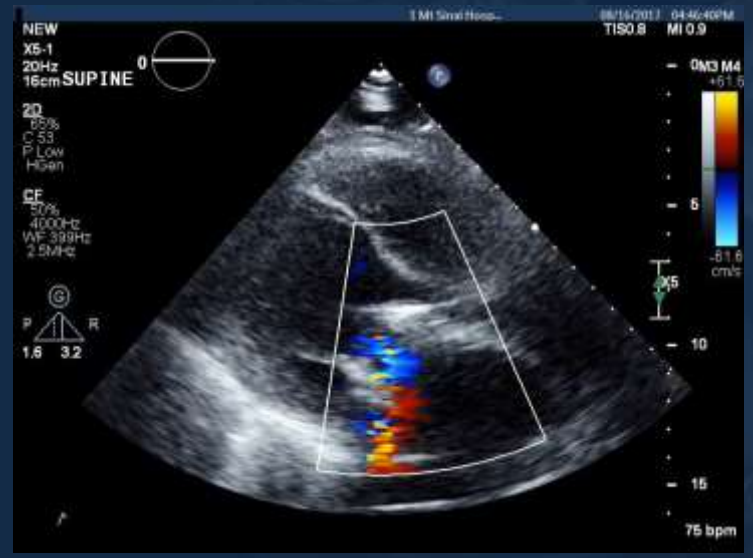


Final Result LVOT Gradient



Post-operative Course

- Extubated on POD 4
- Renal failure requiring CVVH (renal recovery 10 days after the procedure)
- Maintained on low-dose milrinone for two weeks
- Discharged on POD 21
- Died a year post-implant from complications of renal failure



APOLLO TRIAL
TO EVALUATE INTREPID™ TMVR IN PATIENTS WITH SEVERE SYMPTOMATIC MITRAL REGURGITATION

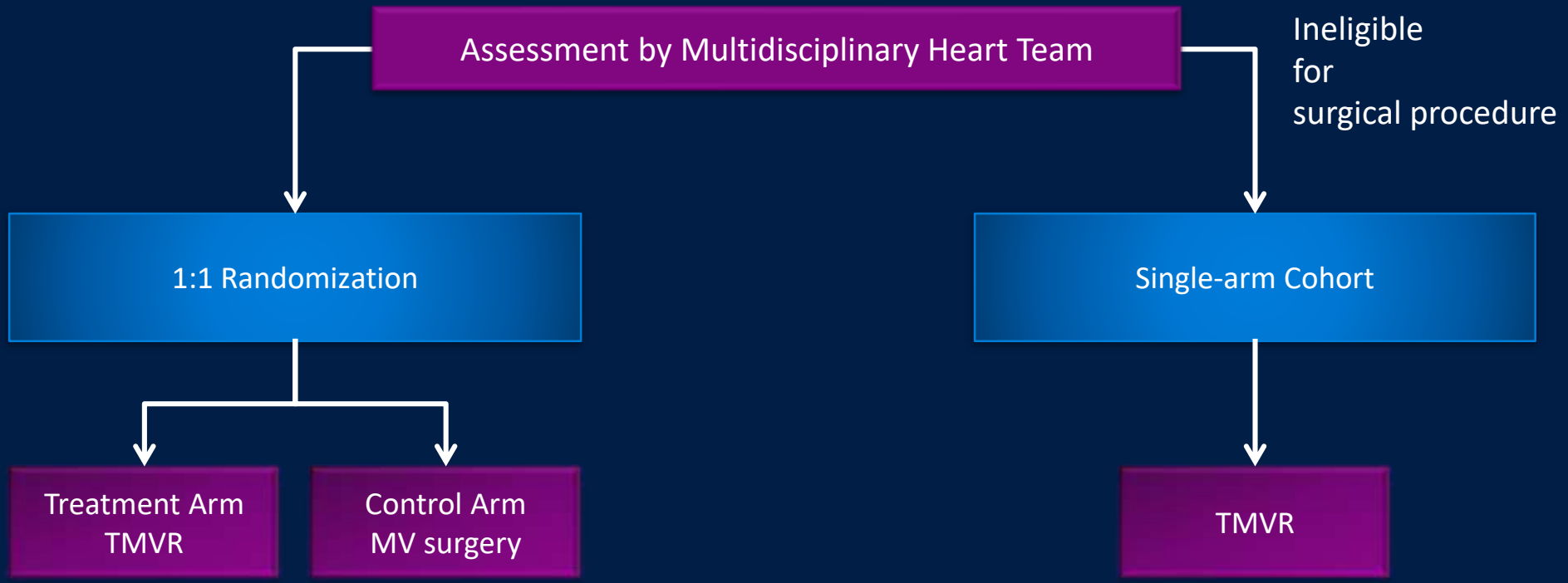
	Randomized Cohort	Single-arm Cohort
Primary Endpoint	• The rate of all-cause mortality, all stroke, reoperation (or reintervention) and cardiovascular hospitalization at 1 year	
Secondary Endpoint	• Composite of all-cause mortality, disabling stroke, acute kidney injury, prolonged ventilation, deep wound infection, reoperation (or reintervention) for any reason and major bleeding at 30 days or hospital discharge whichever is longer • Change in NYHA at 1 year • Quality of Life (QoL) Improvements at 30 days (SF-12) and 1 year (KCCQ) • Echocardiographic assessments of degree of mitral valve regurgitation at 1 year • Days alive out of hospital at 1 year (all hospitalizations) from index procedure • Cardiovascular hospitalization through 1 year	
Follow-up Evaluations	• 30-days, 3-months, 6-months , and annually starting 1 Through 5 years	

APOLLO TRIAL
TRIAL OVERVIEW

Principal Investigators: David Adams and Marty Leon

Study Chair: Michael Mack

Evaluate safety and efficacy of Medtronic Intrepid™ TMVR System in patients with symptomatic mitral regurgitation



APOLLO TRIAL
TRIAL DESIGN

	Randomized Cohort	Single-arm Cohort
Key Inclusion Criteria	• Subject has severe symptomatic mitral regurgitation • Heart Team agrees that patient is a candidate for bioprosthetic mitral valve replacement	
Key Exclusion Criteria	• Predicted risk of operative mortality is <3% at 30 days or has ≥35% risk of mortality or irreversible major morbidity at 30 days • Estimated life expectancy of <24 months due to associated non-cardiac comorbid conditions • Subject with mitral anatomy that would preclude management of the sub-valvular apparatus and/or full chordal sparing • Prior mitral valve surgery including previously implanted mitral valve, ring, or band	• Predicted risk of operative mortality or irreversible major morbidity < 35% and ≥ 50% 30 days • Currently implanted mitral valve • Estimated life expectancy of less than 12 months due to associated non-cardiac co-morbid conditions
Additional Exclusion Criteria	• Prior transcatheter mitral valve procedure with device currently implanted • Anatomic contraindications for Intrepid™ TMVR system (eg., annular dimensions, high risk of LVOT obstruction, transapical access, etc.) • Prohibitive mitral annular calcification • Reduced ventricular function with left ventricular ejection fraction (LVEF) <25% • Hemodynamic instability requiring either inotropic agents or mechanical circulatory support • Need for emergent or urgent surgery	

Transcatheter Mitral Valve Replacement With the Medtronic Intrepid™ TMVR System in Patients With Severe Symptomatic Mitral Regurgitation (APOLLO)

ClinicalTrials.gov Identifier: NCT03242642

Recruitment Status : Recruiting
First Posted : August 8, 2017
Last Update Posted : November 19, 2018

See Contacts and Locations

Sponsor:
Medtronic Cardiovascular

Information provided by (Responsible Party):
Medtronic Cardiovascular

Study Description

Go to

Brief Summary:

Transcatheter Mitral Valve Replacement With the Medtronic Intrepid™ TMVR System in Patients With Severe Symptomatic Mitral Regurgitation (APOLLO)

The safety and scientific validity of this study is
a study does not mean it has been evaluated b
benefits of clinical studies and talk to your healt
details.

s.gov Identifier: NCT03242642

nt Status : Recruiting
ed : August 8, 2017
te Posted : November 19, 2018
acts and Locations

Sponsor:
Medtronic Cardiovascular

Information provided by (Responsible Party):
Medtronic Cardiovascular

United States, New York

North Shore University Hospital — **Recruiting**
Manhasset, New York, United States, 11030
Principal Investigator: Bruce Rutkin, MD
Principal Investigator: Sheel Vatsia, MD

The Mount Sinai Hospital — **Recruiting**
New York, New York, United States, 10029
Principal Investigator: Samin Sharma, MD
Principal Investigator: David Adams, MD

Columbia University Medical Center/NYPH — **Recruiting**
New York, New York, United States, 10032
Principal Investigator: Martin Leon, MD
Principal Investigator: Isaac George, MD

Saint Francis Hospital — **Recruiting**
Roslyn, New York, United States, 11576
Principal Investigator: George Petrossian, MD
Principal Investigator: Newell Robinson, MD

United States, North Carolina

Duke University Medical Center — **Recruiting**

Thank You

Mount Sinai

Mitral Foundation