

# TMVR Step by Step

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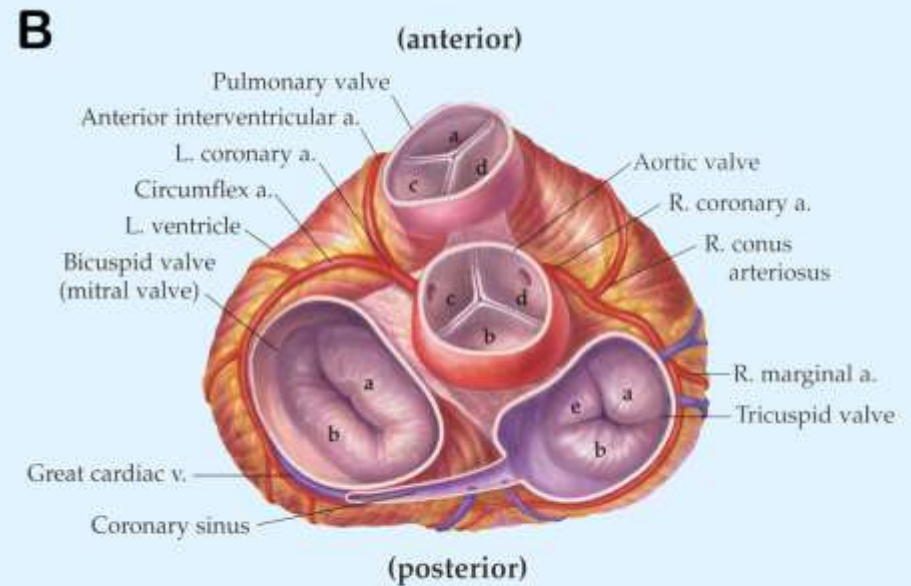
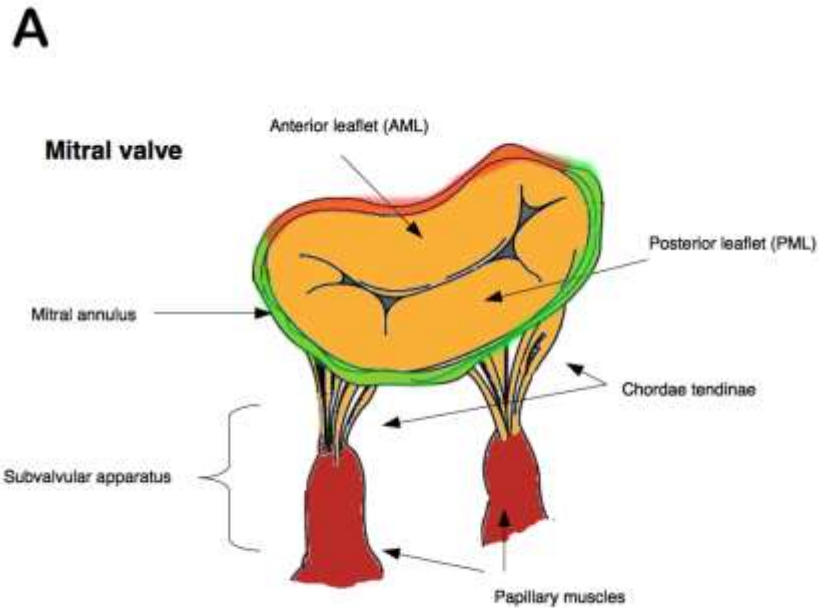
***Speaker's name : Vinayak, Bapat, New york***

***☑ I have the following potential conflicts of interest to report:***

***: Consultant:        Edwards Lifesciences  
                             Medtronic Inc  
                             Abbott  
                             4Tech  
                             4C  
                             Cephea***

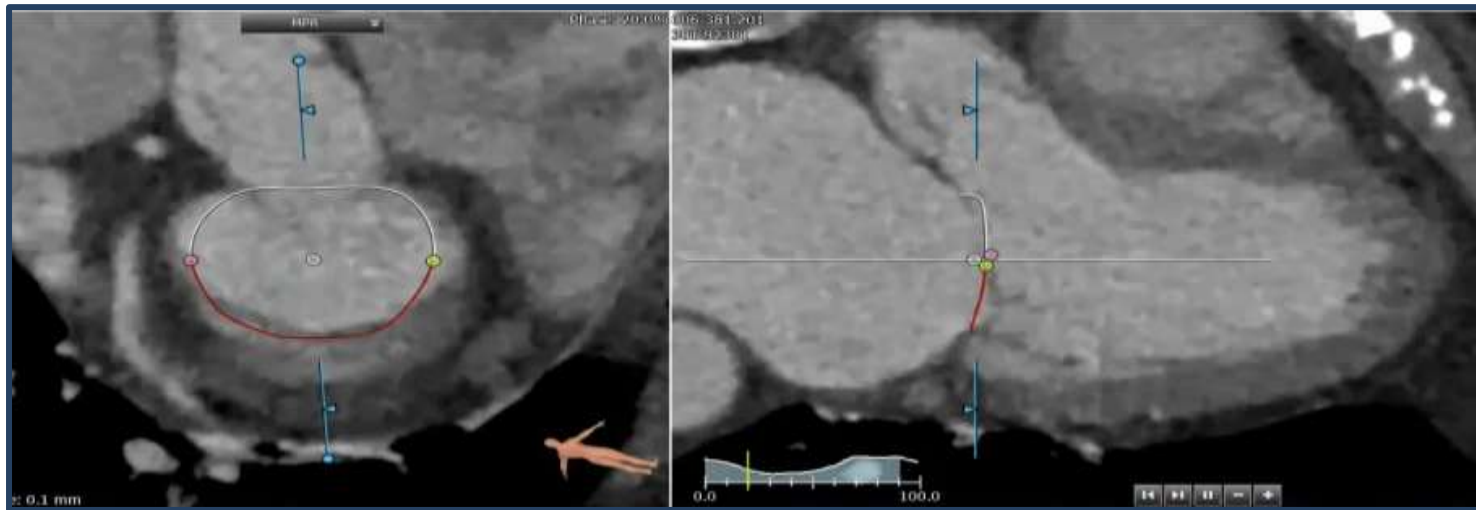
# Transcatheter Native Mitral Repair

## Replacement



# Mitral Valve Anatomy

## Anatomically & Physiologically Challenging



Highly mobile over cardiac cycle  
Very little to “hold on to”

# Challenges with designing a TMVR device

- Device: Complex and large structure
- Leaflets: material, performance
- Frame
  - Multiple components
  - Effect of crimping
  - Mitral annular and LV pressure loops
  - Interaction with blood elements

# TMVR landscape



**Braile Biomedica**



**Braile Biomedica**



**CardiAQ 1<sup>st</sup> G**



**CardiAQ Edwards**



**Cephea**



**Direct Flow Medical**



**Twelve Medtronic**



**M-Valve**



**Edwards Fortis**



**HighLife**



**Navigate**



**Neovasc Tiara**



**PermaValve MID**



**Sinomed**



**Tendyne Abbott**



**SATURN TMVR**



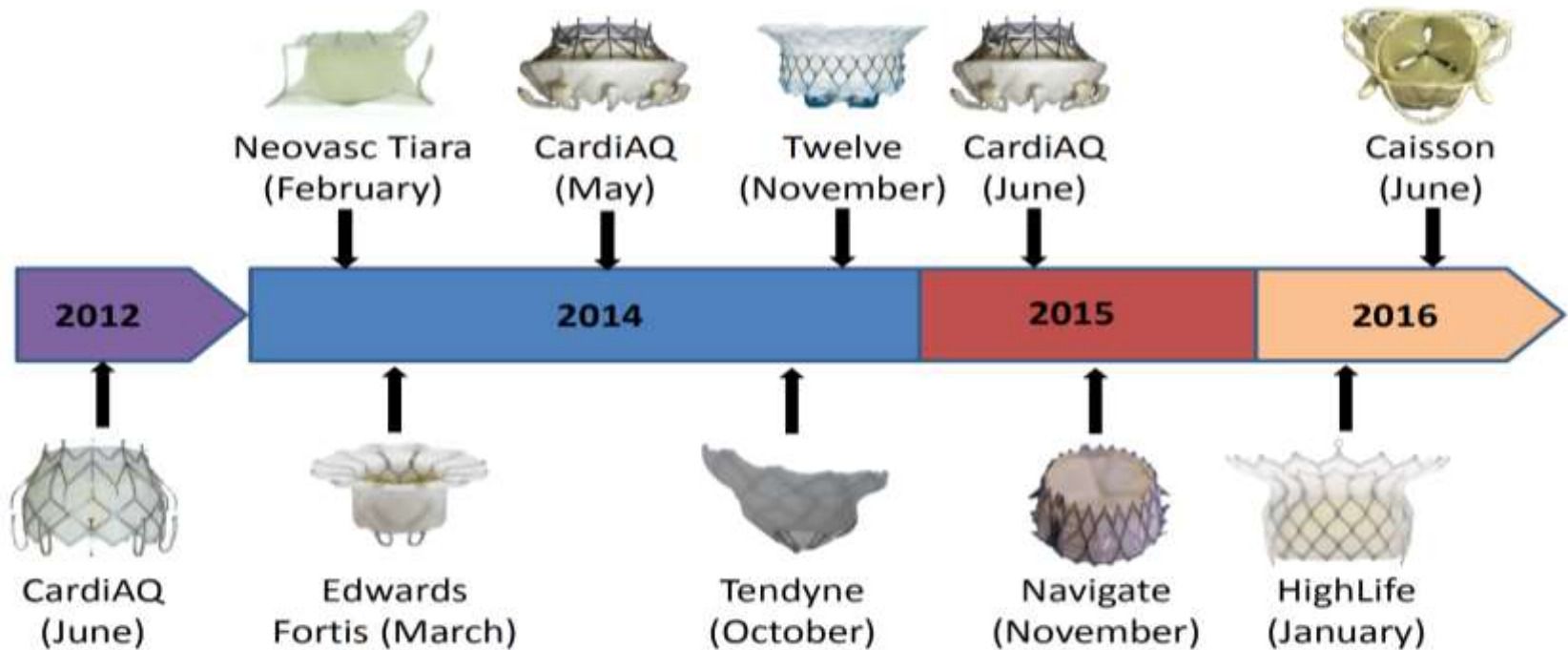
**Valtech CardioValve**



**Caisson**

**Others:** MitraHeal, Mitrasist, Mitraltech, Mehr Medical, Mitracath, Mitralix MAESTRO, Nakostech, St. George ATLAS, Transcatheter Technologies Tresillo

# TMVR timeline – First in Man



# Edwards CardiAQ

## MULTIPLE ACCESS ROUTE

TA or TF

## POSITIONING & CONTROL

Sits higher in the atrium

Minimal LVOTO

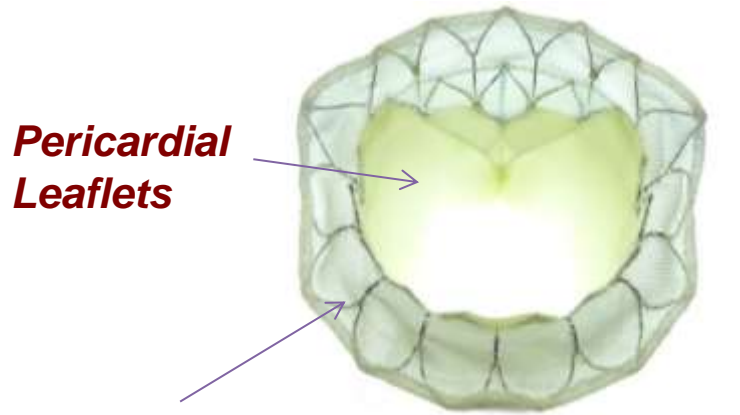
## ANCHORING

- Unique frame designed for annular attachment **without radial force**
- Preserves chords and uses native leaflets



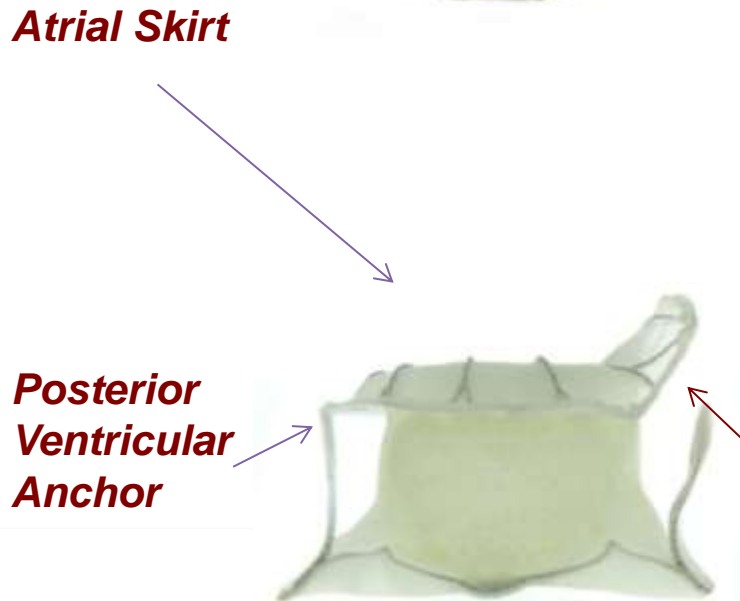


# NeoVasc - Tiara Valve



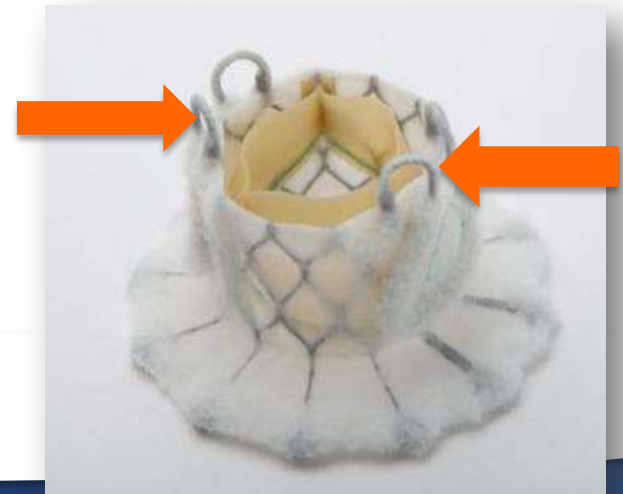
“D” shape Design

1. Help minimize PVL,
2. Avoid LVOT obstruction and
3. Avoid impingement on the aortic valve

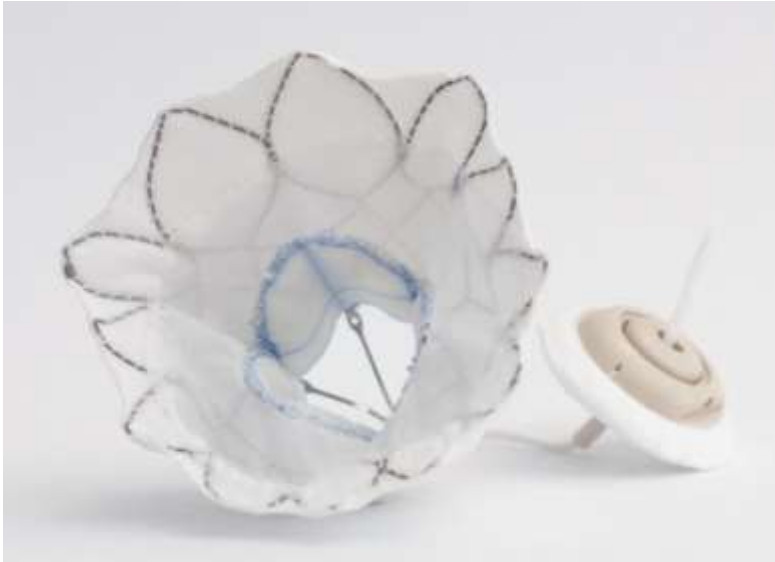


# The Edwards Fortis TMVR

- Bovine pericardial tissue
- Anti-calcification - GLX
- Self-expanding
- Unique anchoring
- At present one size – 29



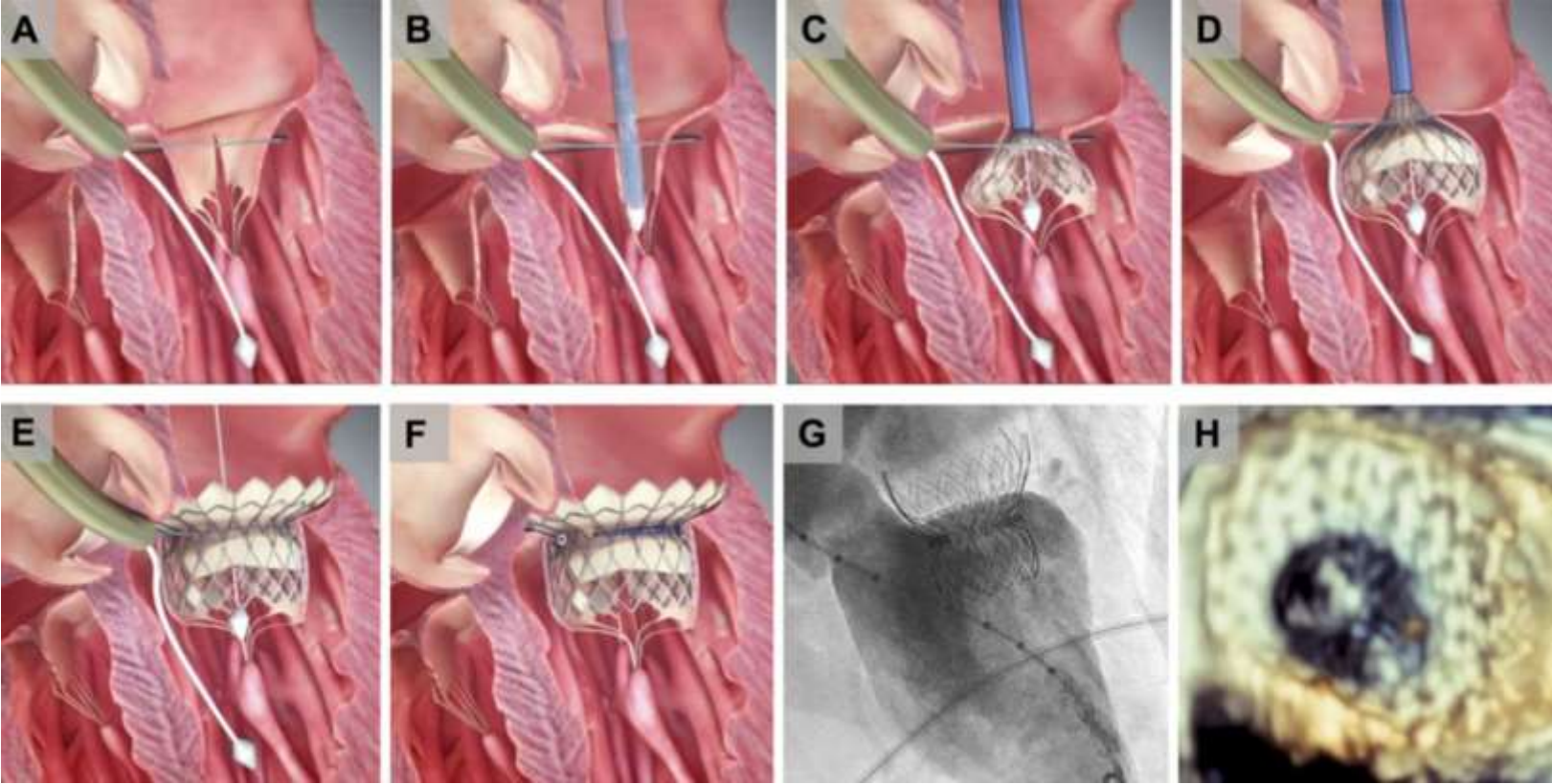
# Tendyne



## Tendyne Device

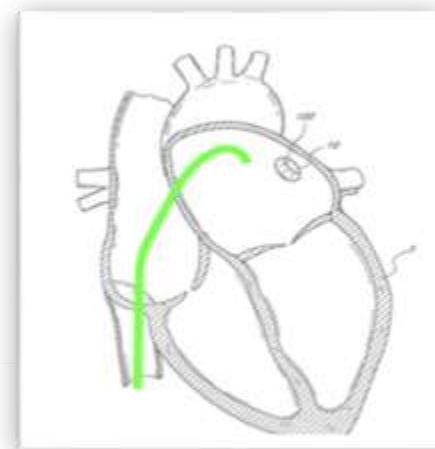
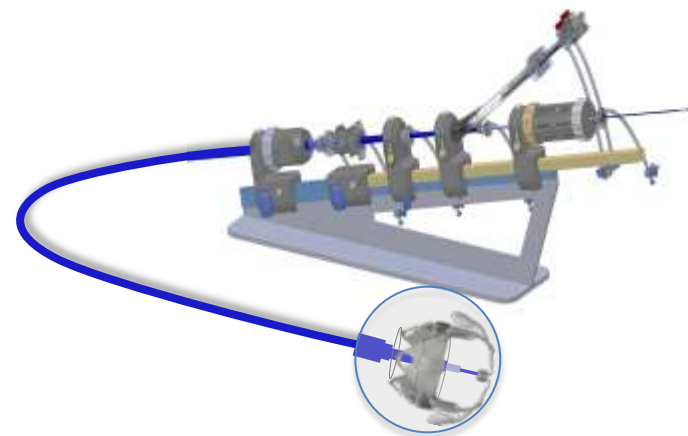
- D-Shaped
- Self-Expanding Nitinol Frame
- Porcine Pericardial Tri-Leaflet Valve
- Left Ventricular Tether to Apex
- Fully Repositionable and Retrievable Mitral Valve
- Multiple sizes

# Highlife





# Caisson: 2 steps



# Patient background

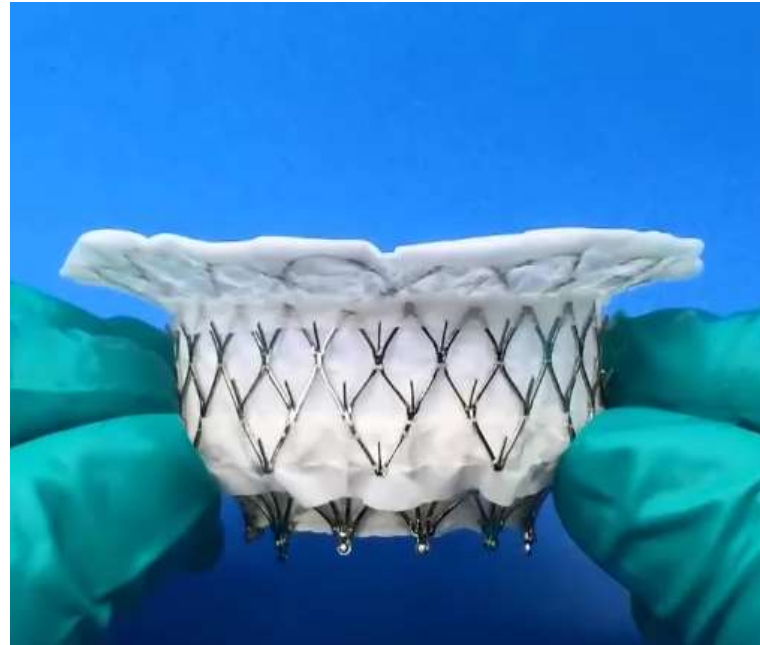
- 63 yo female, 172 cm, 75 kg
- FMR, grade 4+
- NYHA Class III
- LVEF: 23%
- Cardiac history
- Prior aortic valve replacement (19mm Perimount) with moderate stenosis
- Porcelain aorta
- CABG
- Moderate tricuspid regurgitation
- Medical history
- Hypertension
- STS score: 2.5% mortality
- Euroscore II: 9.1%

# Diagnostic echo

FMR, grade 4+



# Medtronic Intrepid TMVR Dual Stent Design

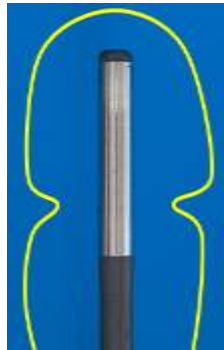


1. Conformable Outer Stent engages the annulus providing fixation & sealing while isolating the inner stent from the dynamic anatomy
2. Circular Inner Stent houses a 27 mm tricuspid bovine pericardium valve



# Medtronic Intrepid TMVR

## Hydraulic Deployment of Self-Expanding Stent



*Step 1.  
Advance  
across valve*



*Step 2.  
Deploy brim*



*Step 3.  
Retract to  
desired position*



*Step 4.  
Expand  
fixation ring*

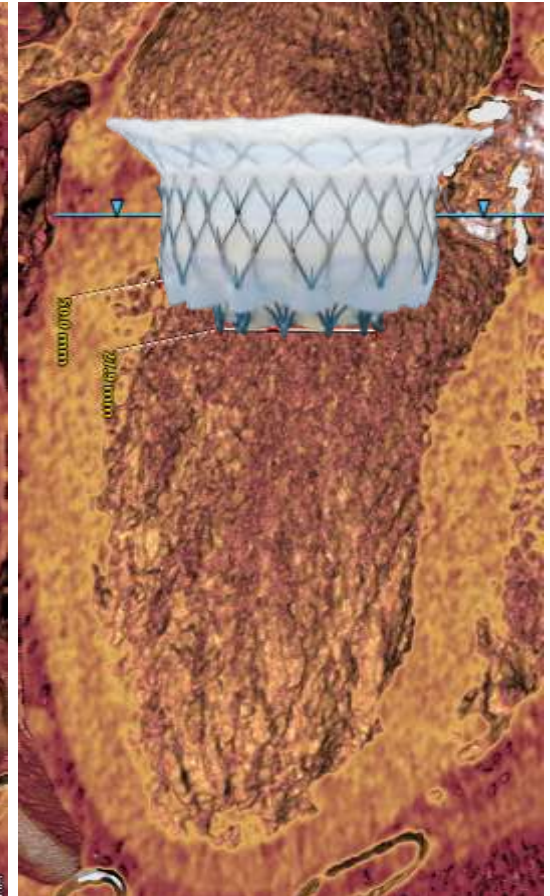
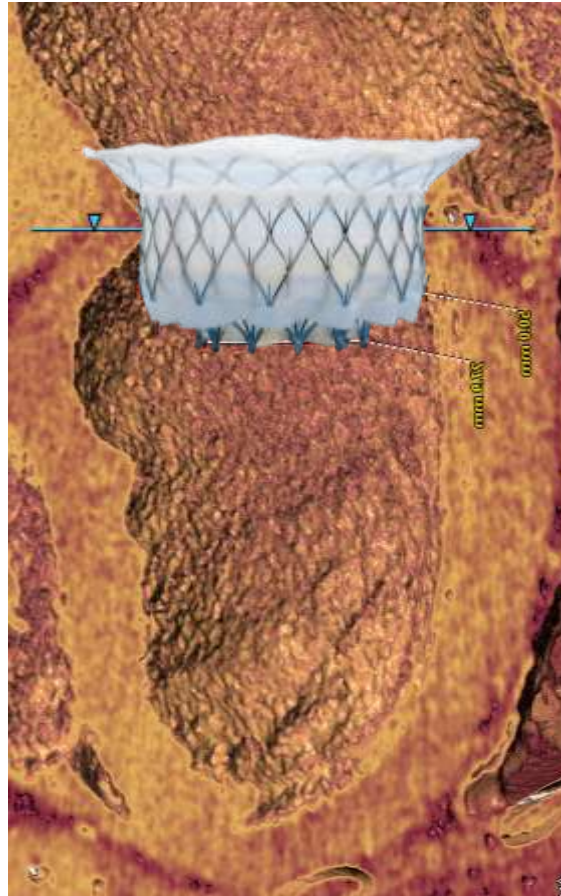


*Step 5.  
Release*

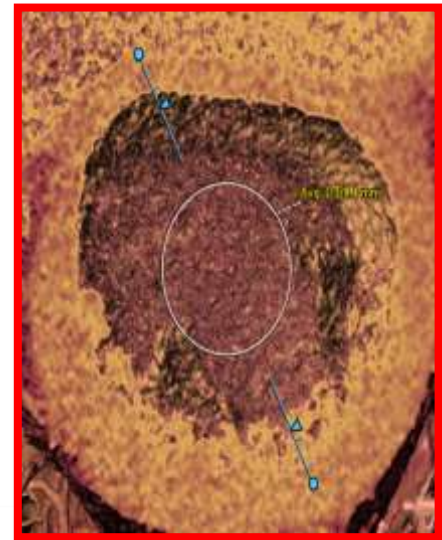
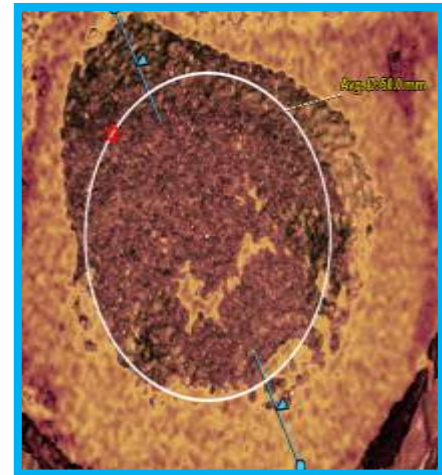
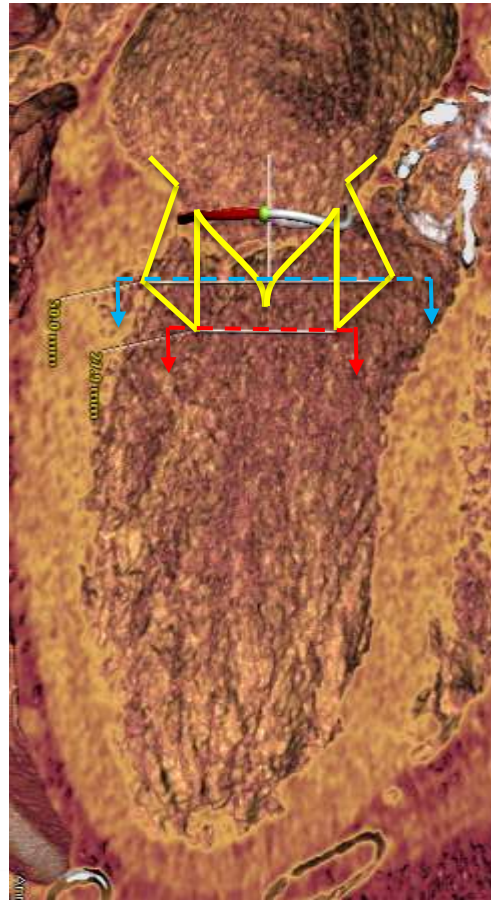
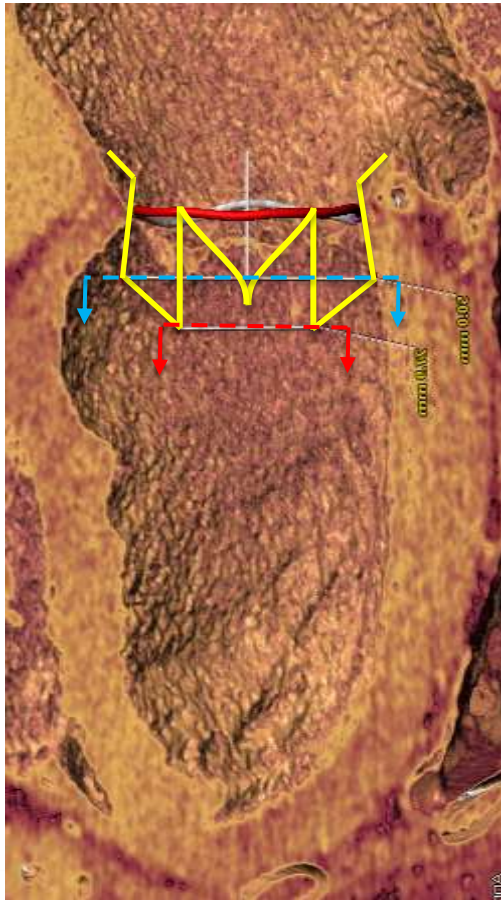


# Annulus sizing

- 50 mm implant
- 25% diameter oversizing
  - 22% perimeter oversizing
  - 13% CC compression
- Patent LVOT

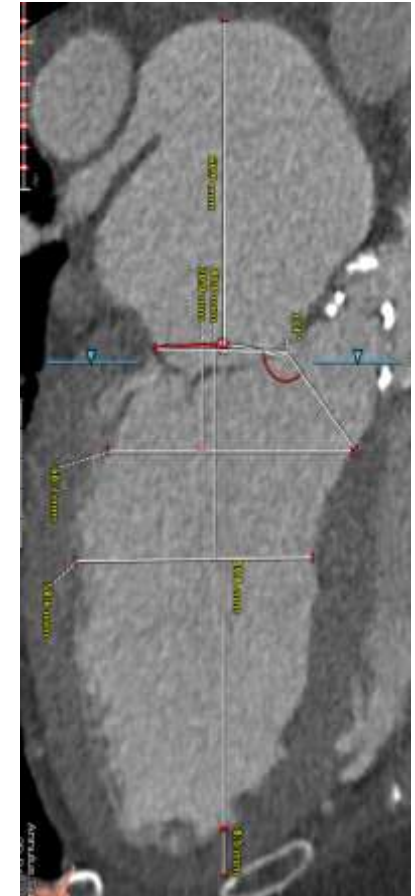
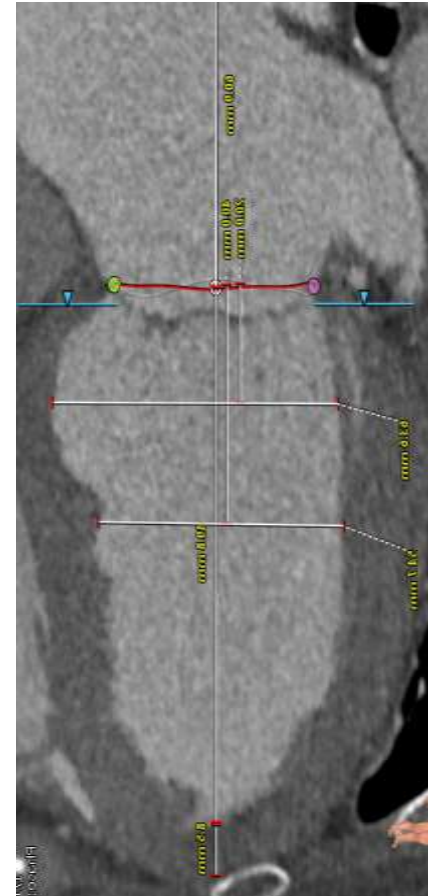


# LVOT & LV assessment



# LVOT & LV assessment

- LV volume score: 248
- Wide 134° aortomitral angle
- 8.5 mm wall at incision site

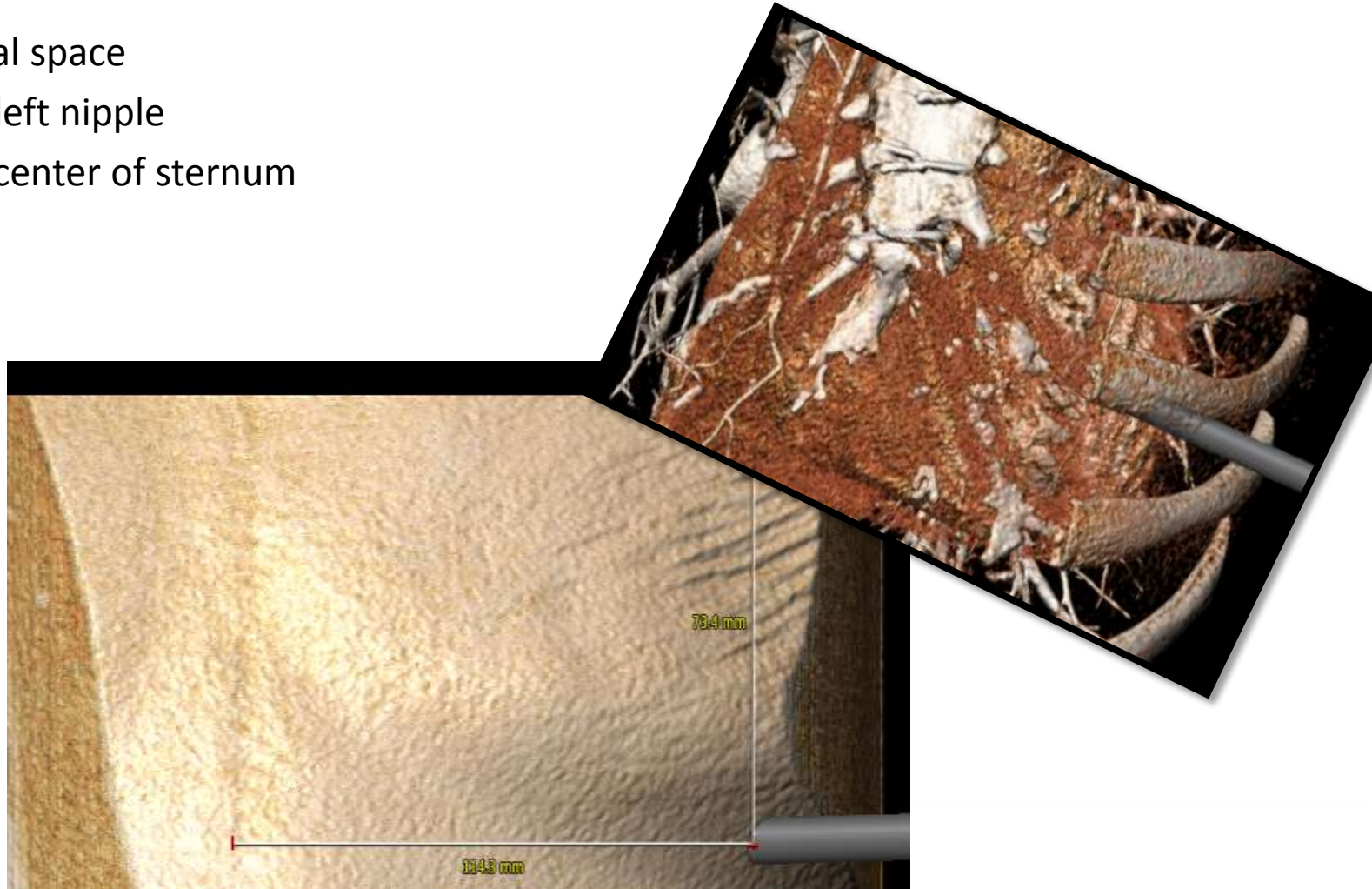


# Surgical planning: Incision location

4<sup>th</sup> intercostal space

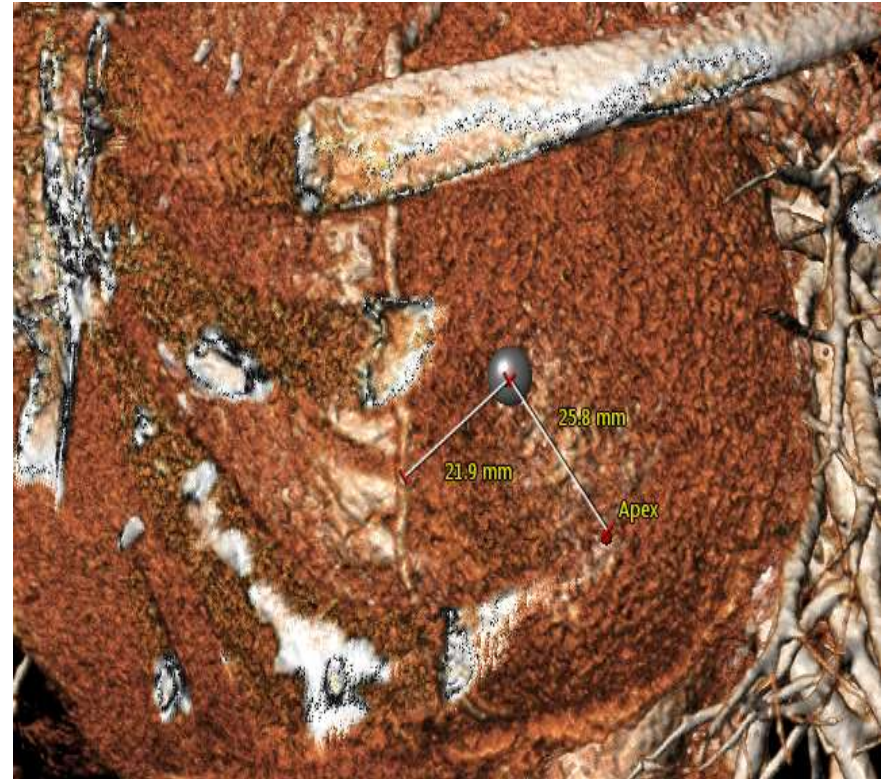
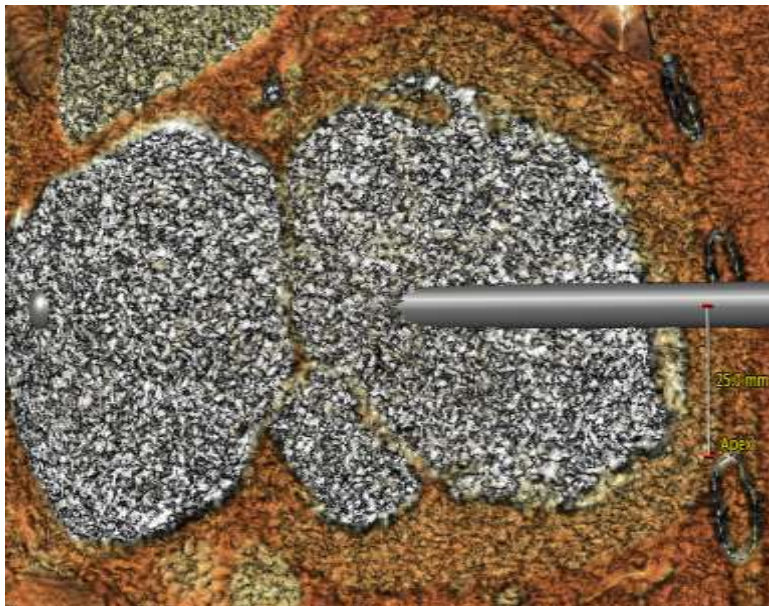
8 cm below left nipple

11 cm from center of sternum

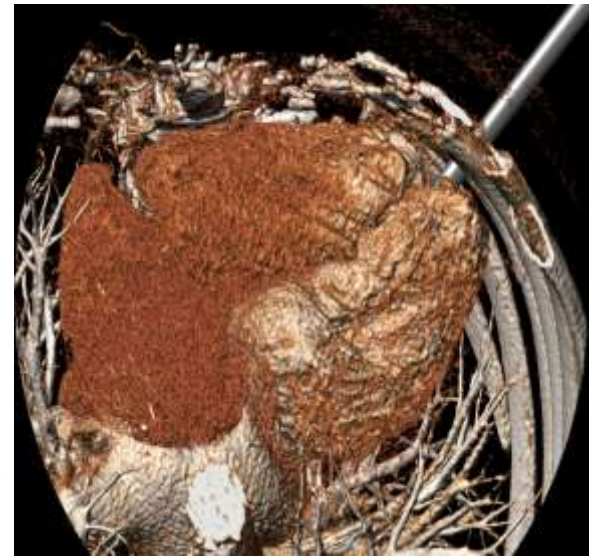


# Apical access site

- 2.5 cm from true apex
- 2 cm from LAD

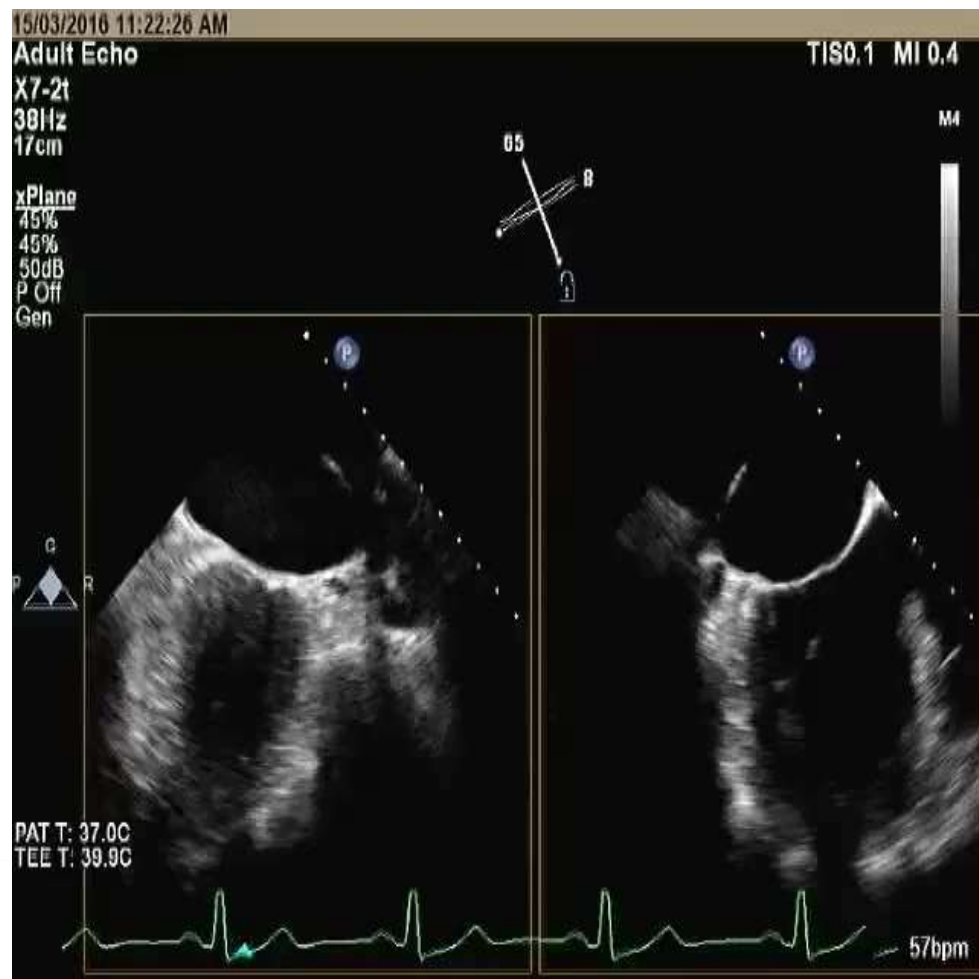


# Catheter angles



# Echo confirmation of incision location

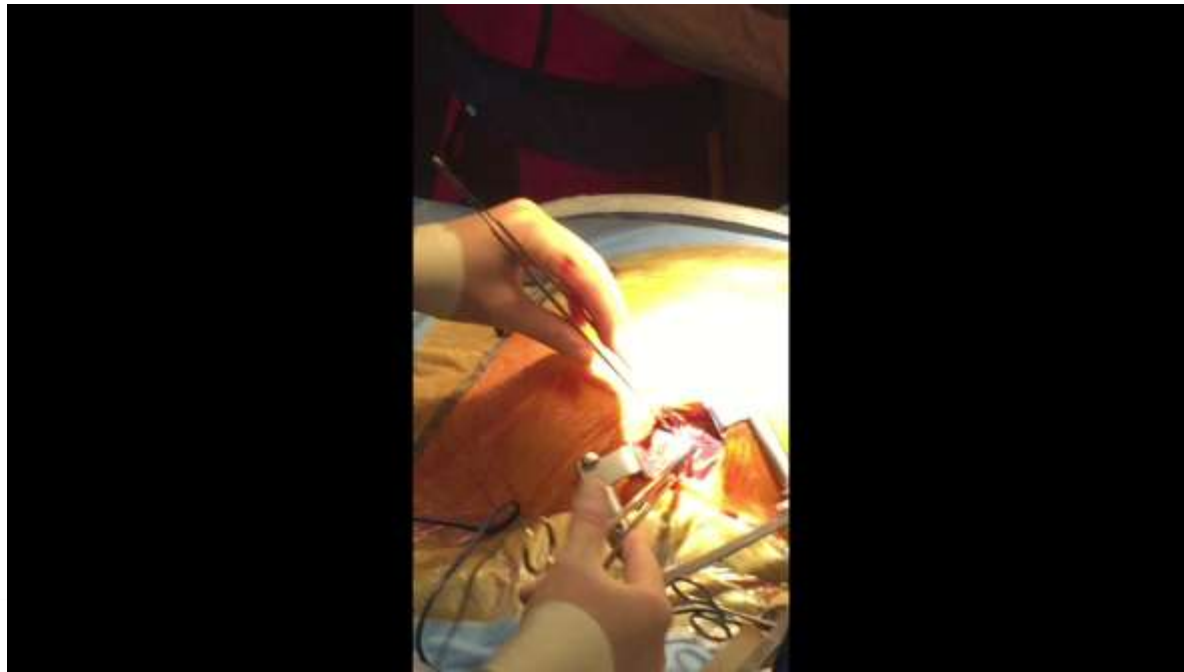
Finger poke at proposed apical incision location visualized on echo



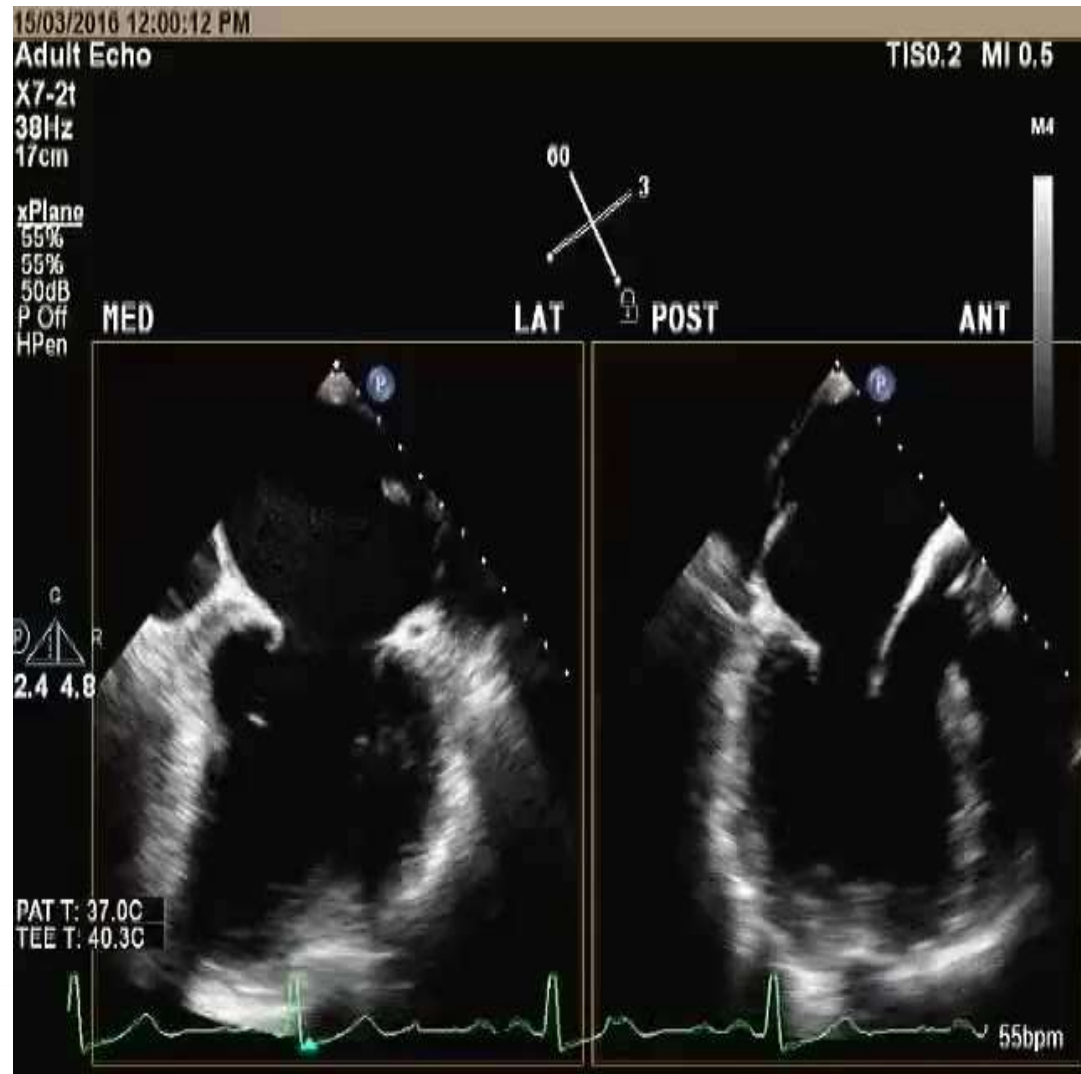


# Access site

1. Incision location from base of sternum and from the nipple
2. Trans-apical like incision
3. 2 purse-strings

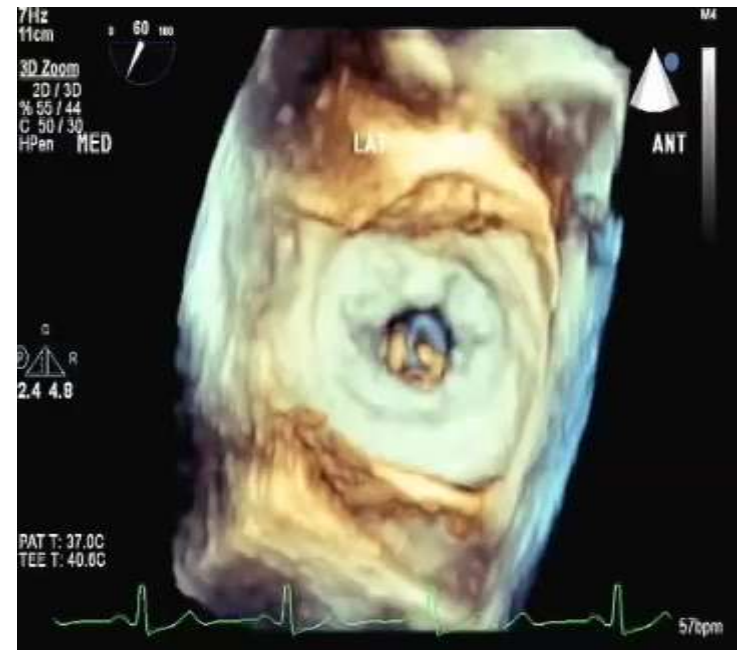
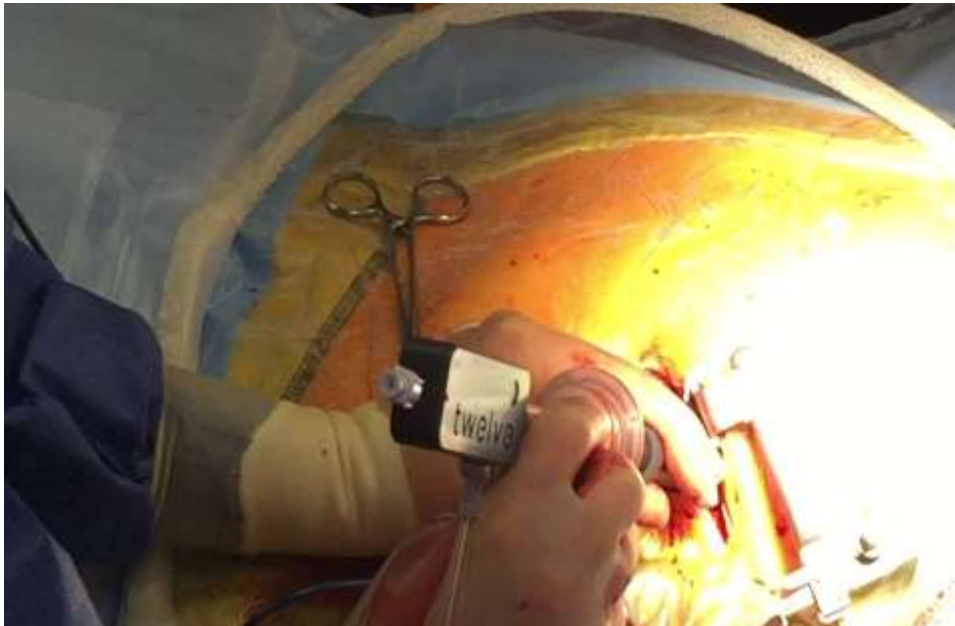


Good communication  
between echocardiologist &  
surgeon



# Steering confirmation at stage 1

1. Switched to 3D view
2. To fine tune how handle movements affected tip position with respect to MV anatomy

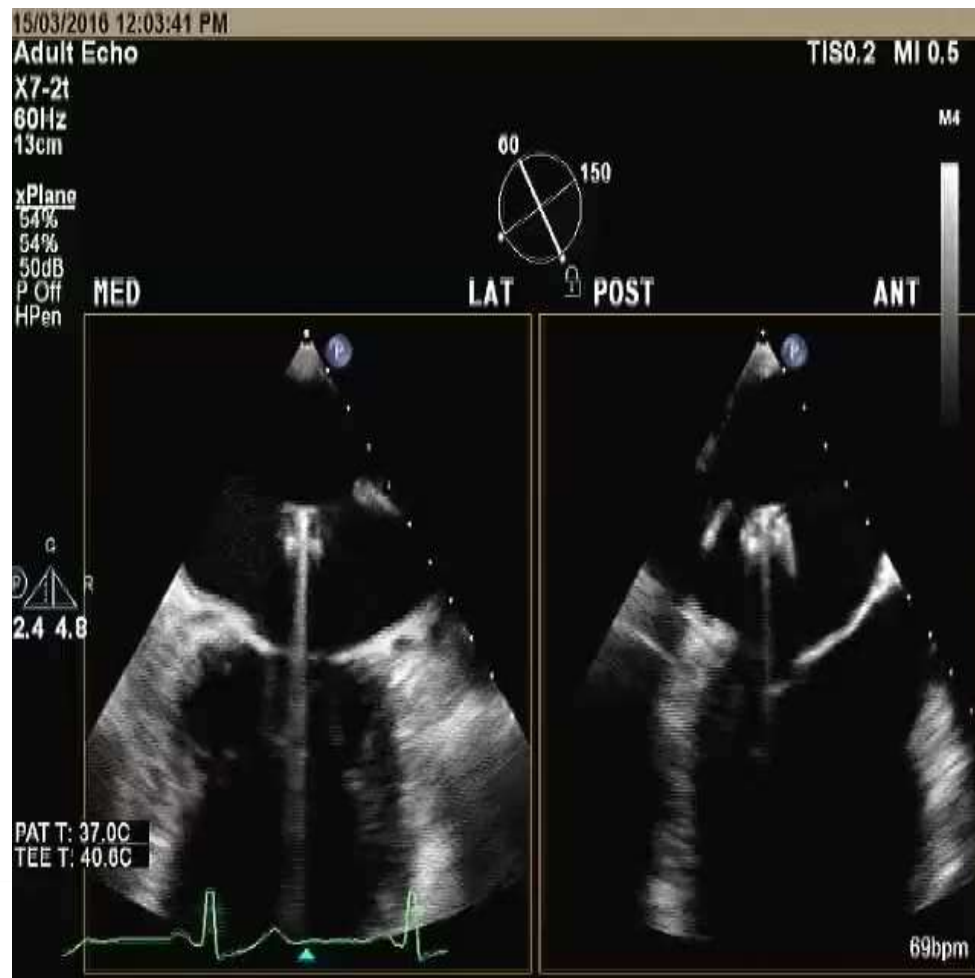


## Expansion to stage 2

- Viewed primarily on fluoro
- Monitored on echo as well

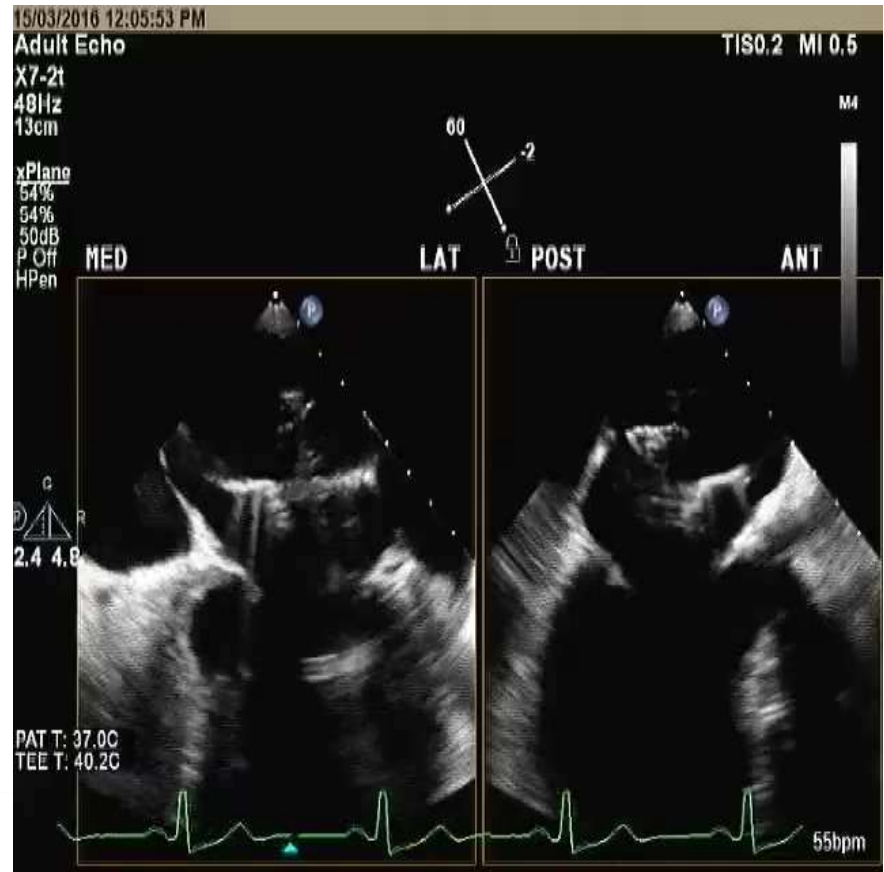
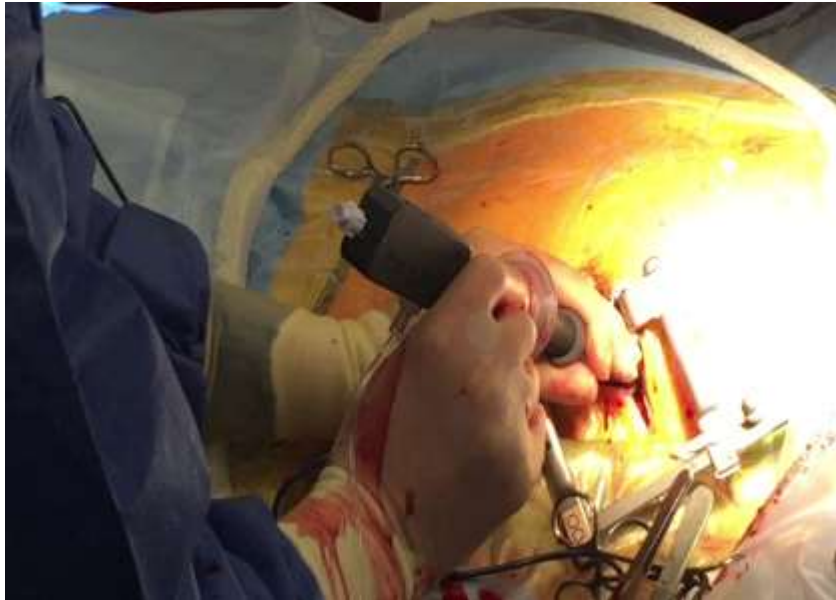


## Expansion to stage 2 - echo



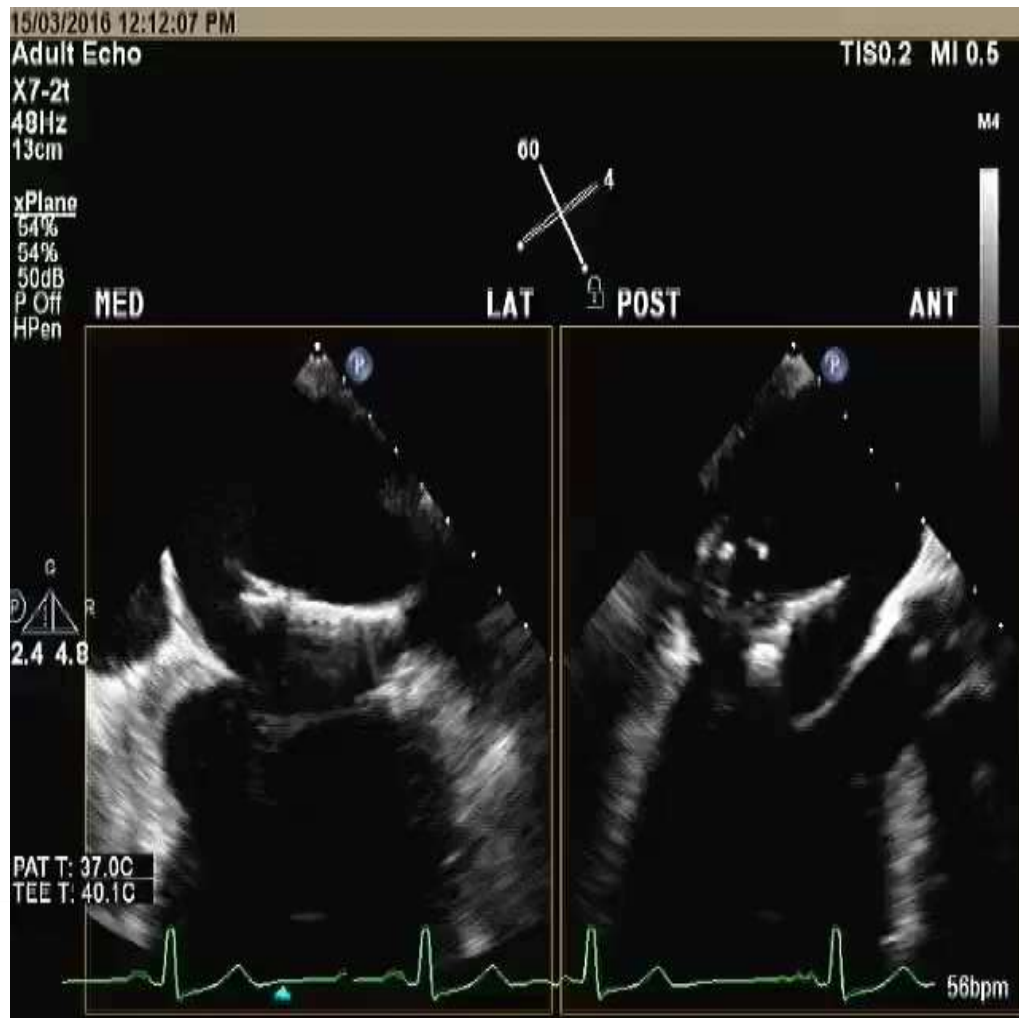
## Visualization at stage 2

Rotated delivery catheter handle to better visualize brim



## Expansion from stage 3 to stage 5

- Hold respiration & began rapid pacing
- Retracted to Stage 3
  - Confirmed position
- Expanded to Stage 4
  - Confirmed position
- Expanded to Stage 5
  - Implant released and fully deployed
- Stopped pacing
  - 30 sec total
  - 12 min from catheter insertion to functional implant



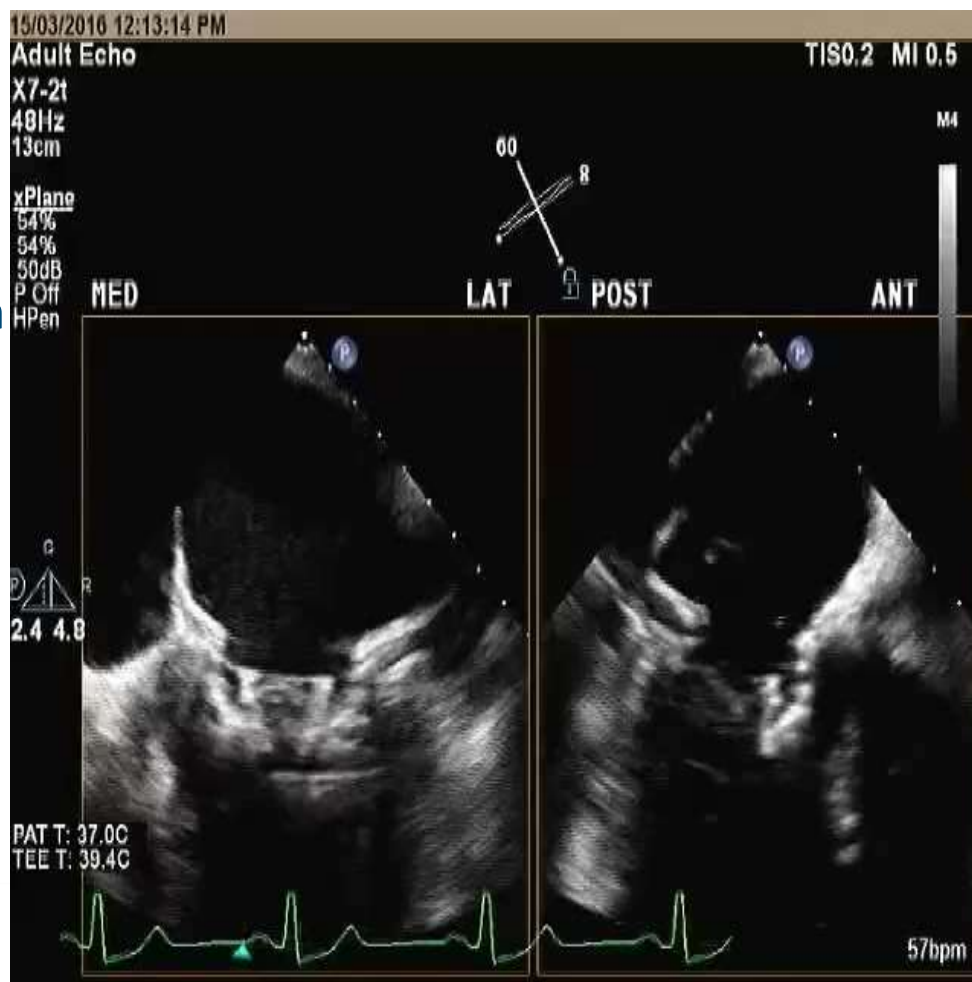
## Expansion from stage 3 to stage 5





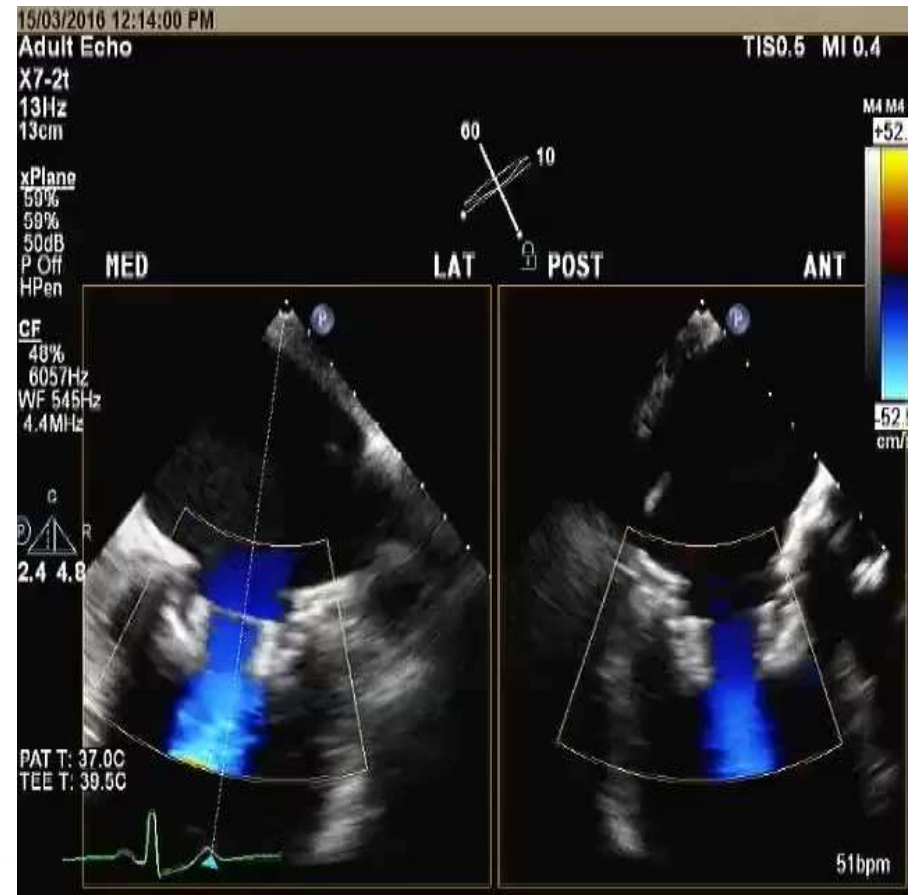
## Removal of delivery catheter

- Retracted delivery catheter
- Removed sheath and closed incision

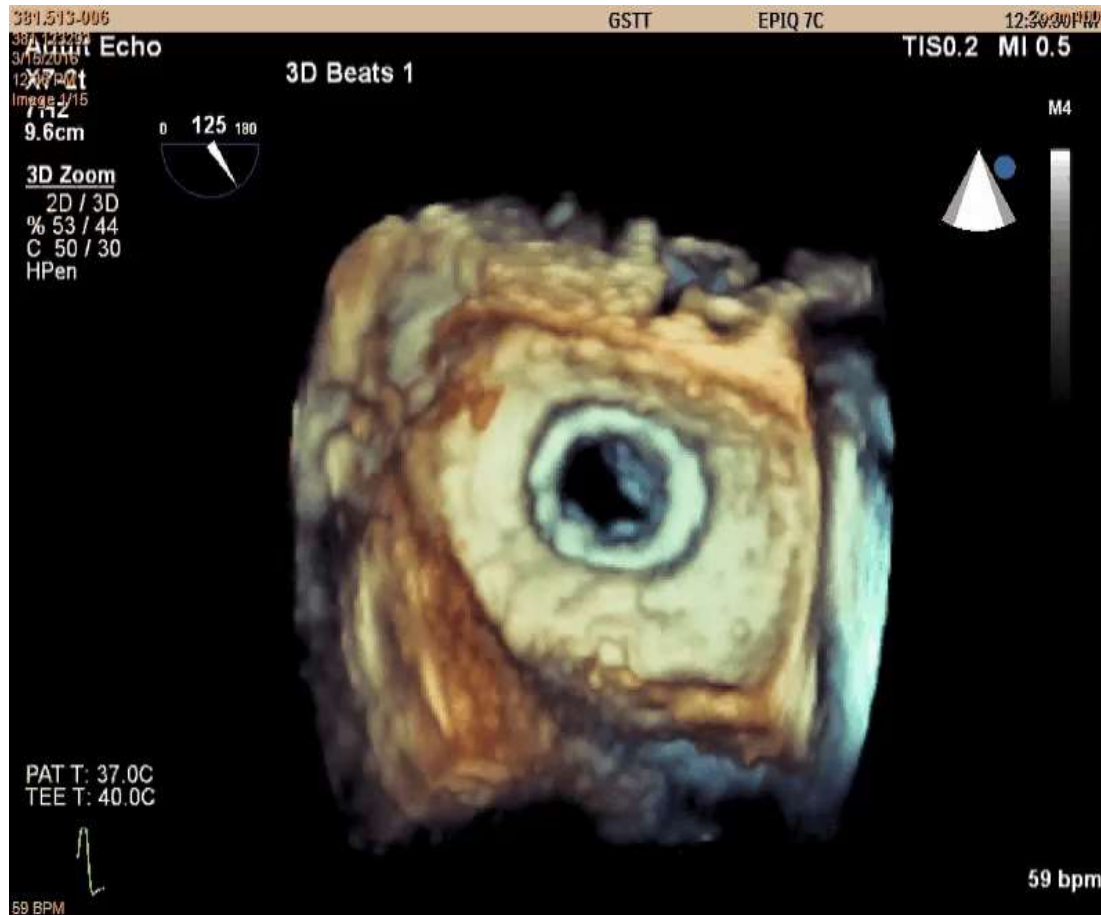


# Results

- Accurate placement
- Good valve function
  - Trace tripoint leak
  - Mean MV gradient: 3 mmHg
- Good paravalvular sealing

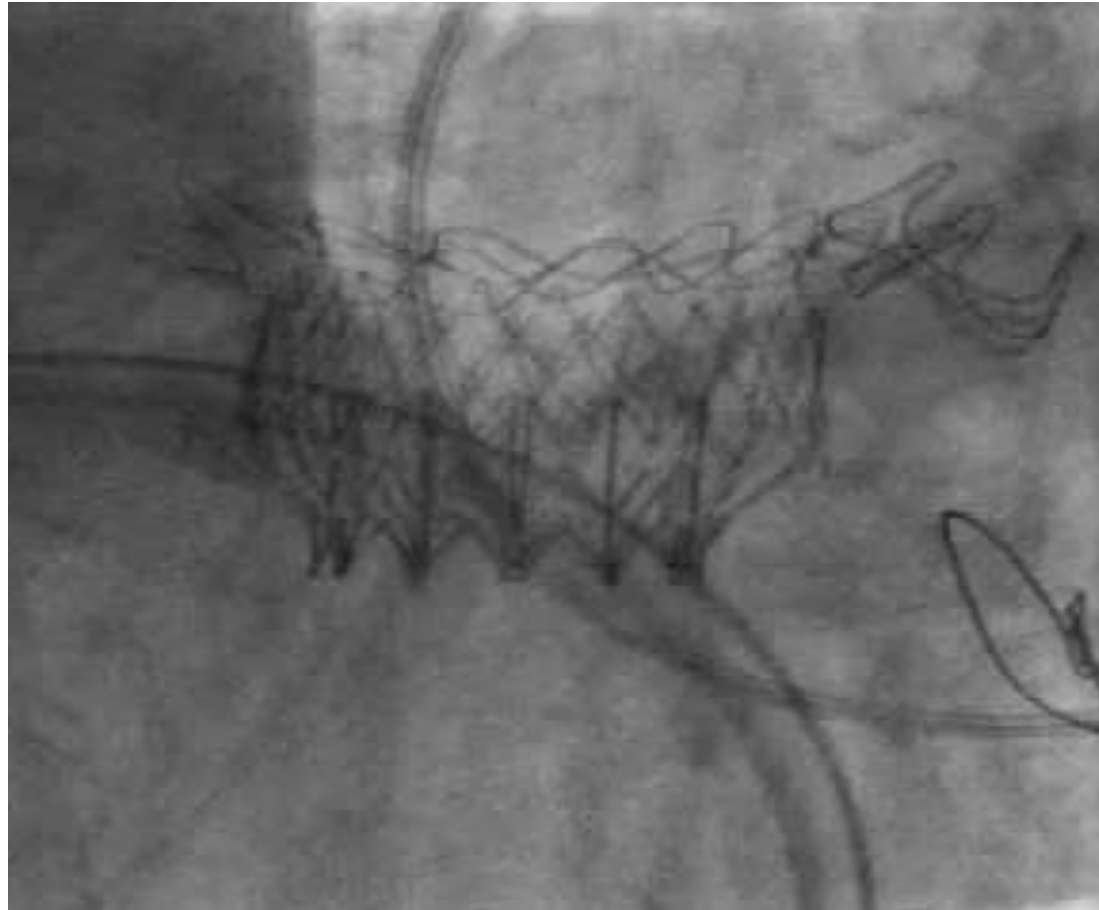


# Result

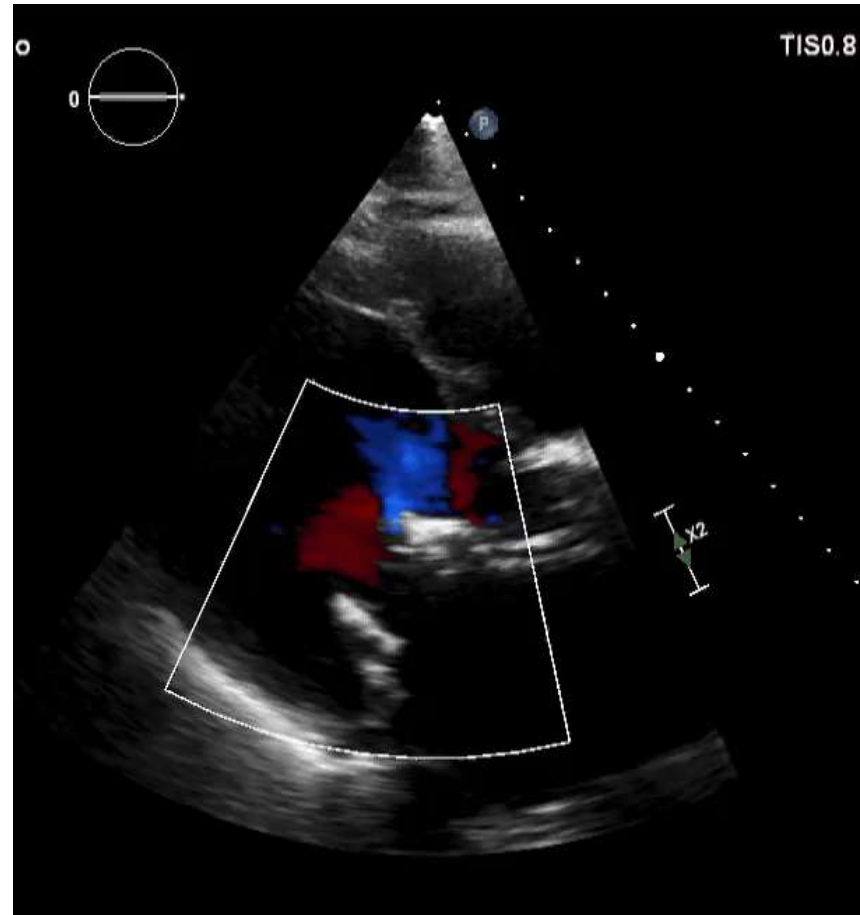


- Implant conformed to the anatomy

# Implant conformed to the anatomy



- Patent LVOT
  - Mean LVOT gradient: 2 mmHg



## Procedure Time

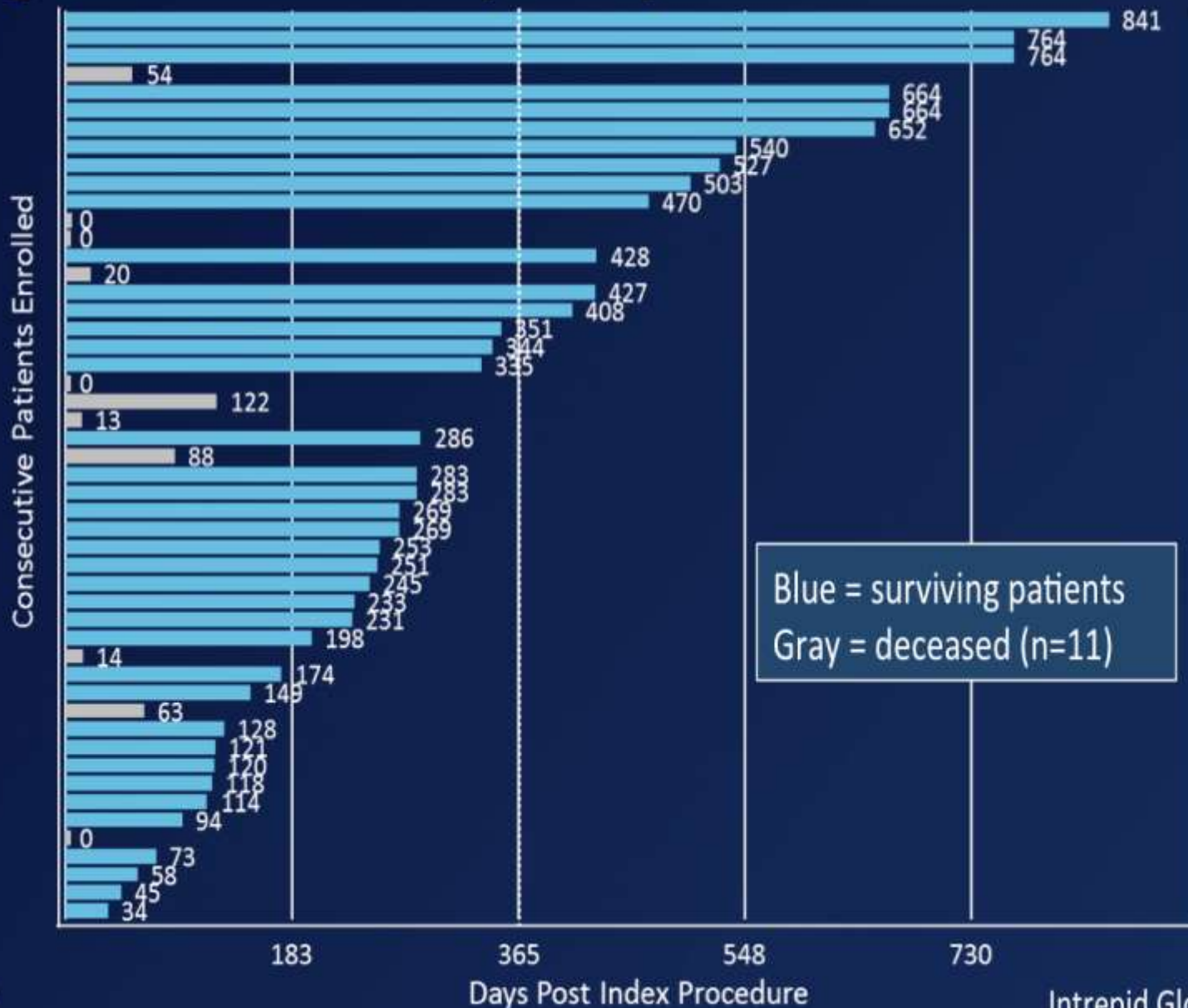
- Apical access (puncture to closure): 23 min
- Placement (insertion to final deployment): 12 min
- Rapid pacing for full deployment: 30 sec
- Skin-to-skin: 114 min

# One year

- Stable position
- Good valve function
  - Mean MV gradient: 7 mmHg
- No paravalvular leak

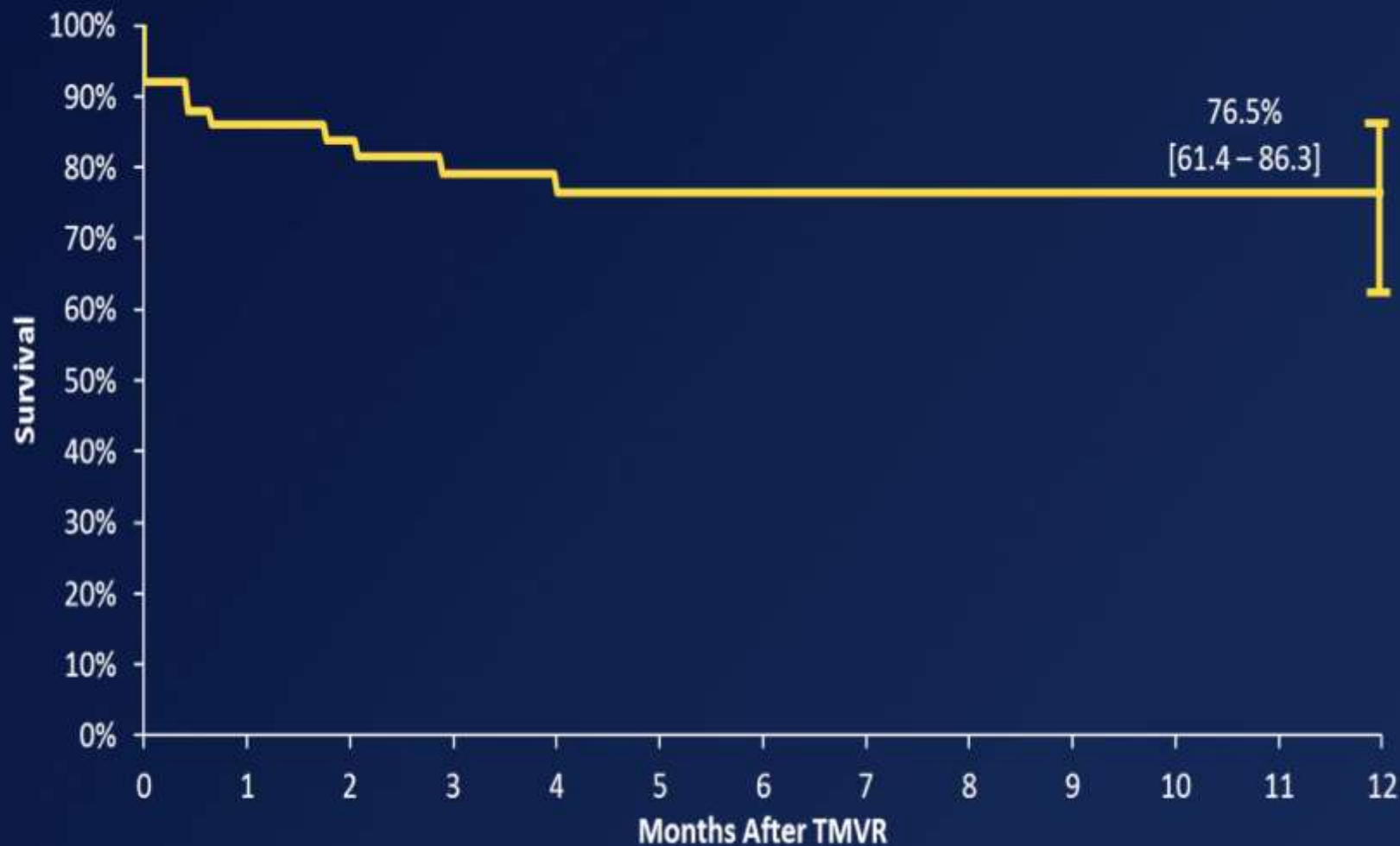


# Long-Term Survival (n=50)





# 1-Year Survival



Number at risk:

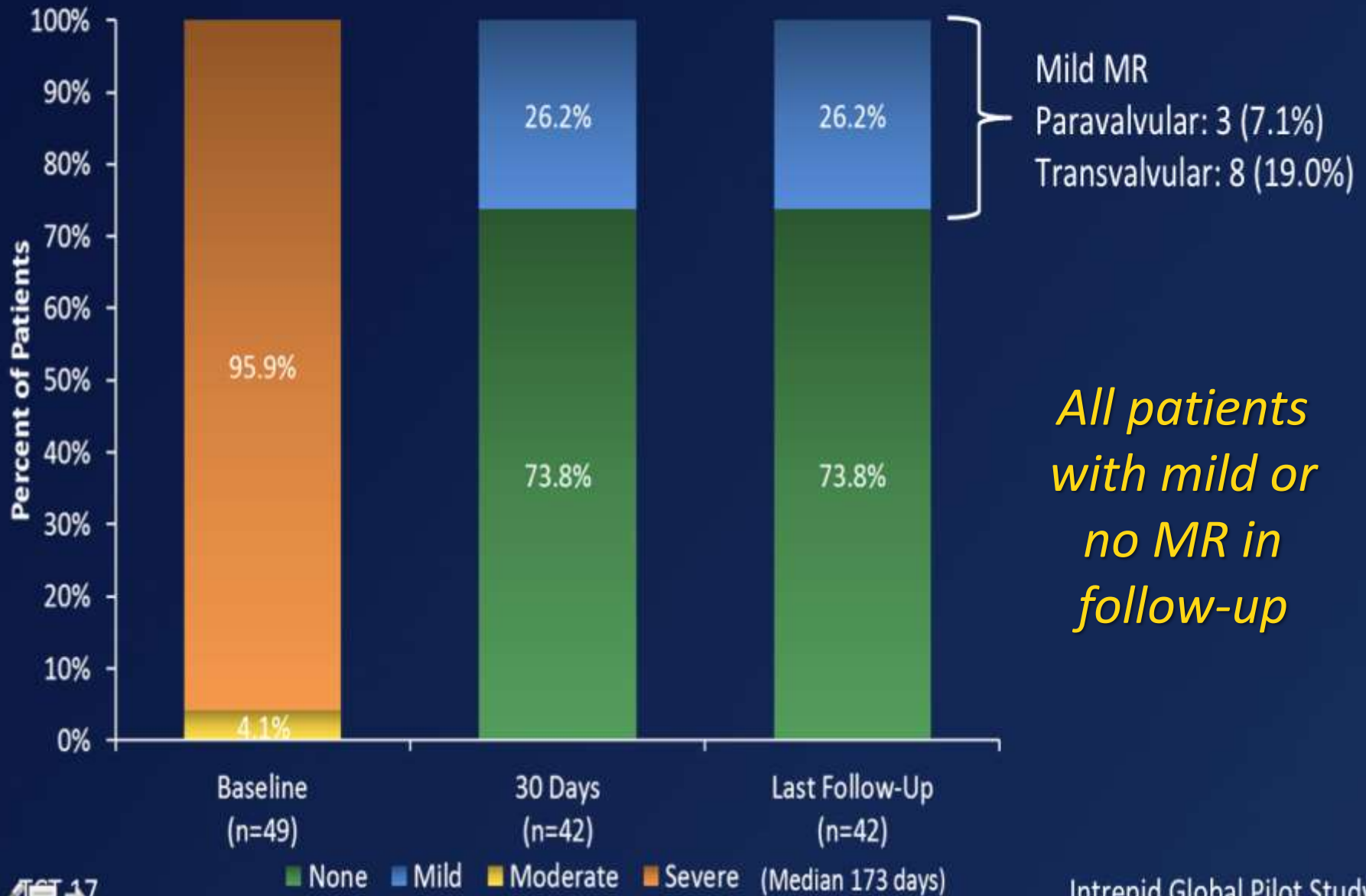
50

41

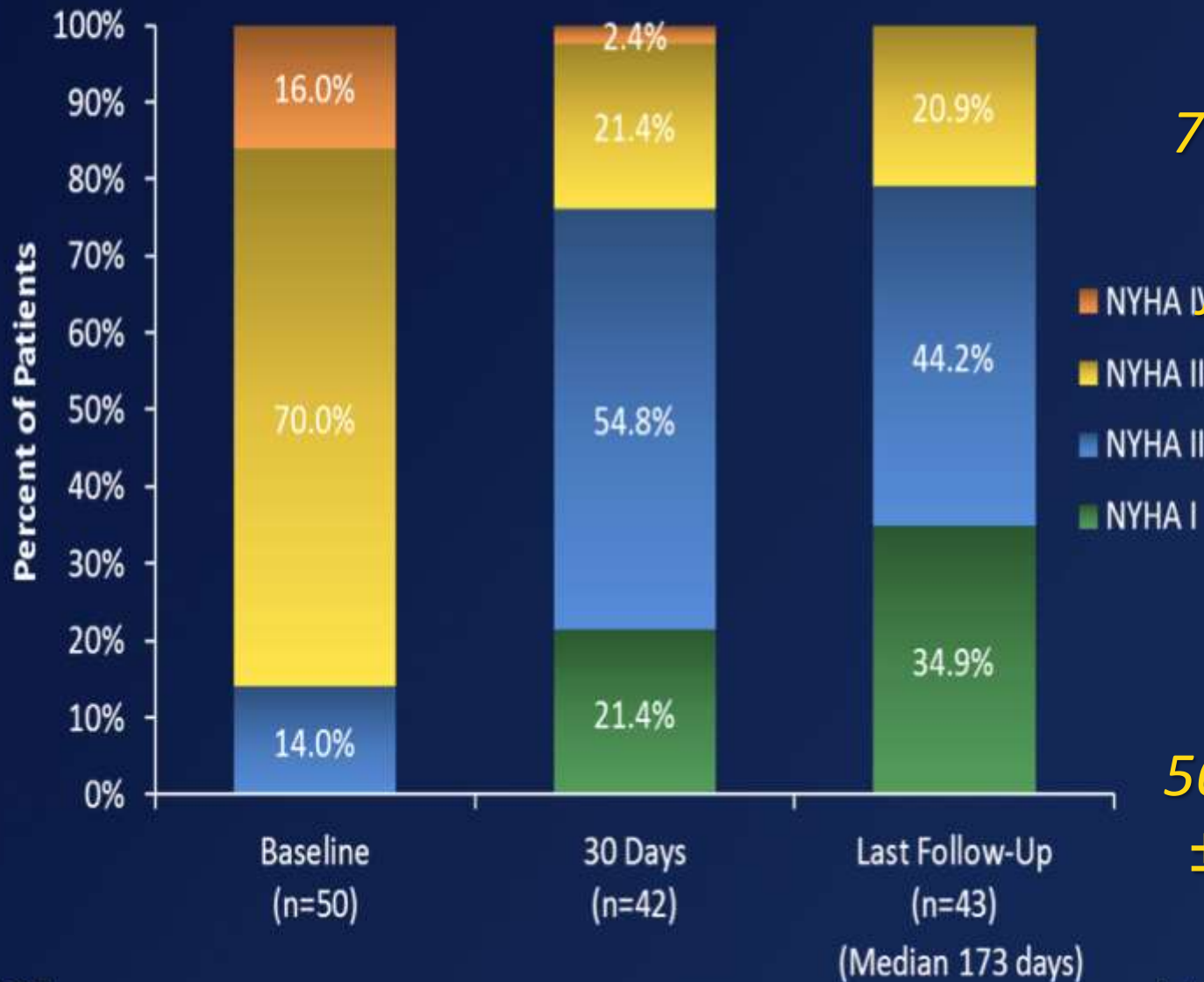
21

10

# Mitral Regurgitation Severity



# New York Heart Association Classification



*79% NYHA I  
or II in  
follow-up*

*MLHFQ  
(n=13)  
56 ± 27 vs. 32  
± 22 p=0.01  
10/13*

# Data Summary (n=50)

- Device implant success in 48/49 (98%)
- 30-day mortality = 14%
  - 3 from apical bleeding, 3 from CHF, 1 from malposition
- One-year survival = 77%
  - 3 SCDs in patients with low EF and no ICDs
  - No death after 180 days
- No device malfunction, hemolysis, or thrombosis
- No or mild MR in all survivors
- 79% of patients in NYHA class I or II in follow-up