



# Update on Transcatheter MV Replacement

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**STS/EACTS Latin American Meeting  
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# Disclosures

- **Abbott Vascular: Advisory Board / Research**
  - National Co-PI: Tendyne in Mitral MAC Trial
  - Executive Committee: SUMMIT trial
- **Boston Scientific: Consultant / Research**
  - National Co-PI: REPRISE IV trials
- **Claret Medical: Consultant**
- **Cryolife: Consultant / Research**
- **Edwards Lifesciences: Advisory Board / Research**
  - National Co-PI: ACTIVE Trial (Cardioband)
- **Gore Vascular: Consultant**
- **Jenavalve: Consultant / Research**
  - National Co-PI: TAVR trial



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# In 2018, The Toolbox for MR



# TAVR

vs.

# TMVR



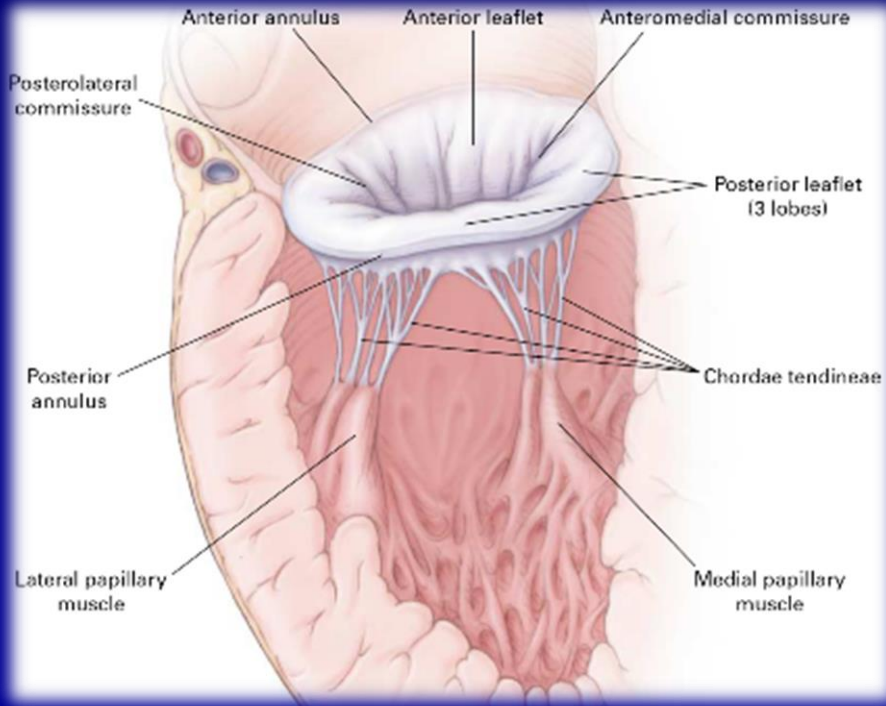
*Annulus Size,  
Leaflet Calcification*



*Annulus Size, Shape, Excursion,  
Leaflet Size, Thickness, Tenting  
Sub-valvular Apparatus  
Circumflex Coronary Artery  
LV Size, Geometry, Function  
Risk of SAM  
Dynamic environment*

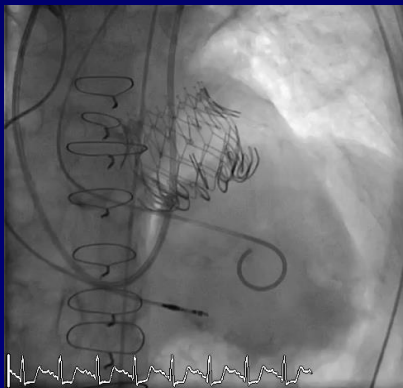


# Design Goals for TMVR



- Complete elimination of MR
- Minimize risk of LVOT obstruction
- Minimize risk of paravalvular leak
- Address wide range of patient sizes
- Durability
- Ease of implant
- Trans-septal

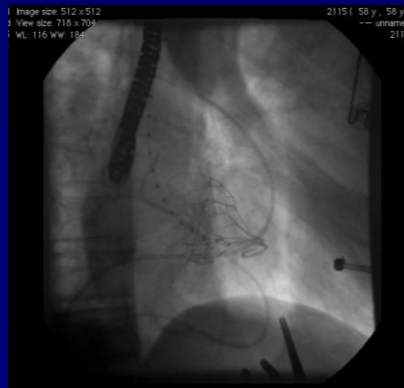
# Transcatheter MVR Systems in Human Use



**Edwards CardiAQ**



**Medtronic Intrepid**



**Abbott Tendyne**



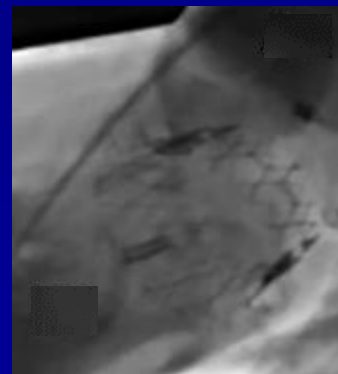
**Neovasc Tiara**



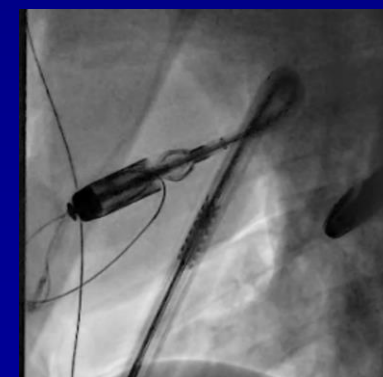
**HighLife**



**Caisson**



**NaviGate**

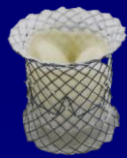


**Mitraltech Cardiovalve**





# TMVR Landscape – 2018 (partial)



Braile  
Biomedica



Braile  
Biomedica



CardiaQ  
Edwards



Cephea



Intrepid  
Medtronic



M-Valve



HighLife



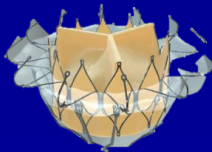
Navigate



Neovasc  
Tiara



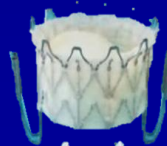
PermaValve  
MID



Sinomed



Tendyne  
Abbott



SATURN  
TMVR



Mitraltch



Caisson



Sapien M3  
Edwards

# Design features

*Courtesy of John Webb*

	CardiAQ	Fortis	Tiara	Tendyne	Intrepid	HighLife	Caisson
Nitinol frame	✓	✓	✓	✓	✓	✓	✓
Trileaflet pericardial valve	✓	✓	✓	✓	✓	✓	✓
Asymmetric valve	-	✓	✓	✓	-	-	✓
Fixation	anchors	paddles	anchors	tether	barbs	ring	feet
Apical access	✓	✓	✓	✓	✓	✓	-
Transseptal access	✓	-	-	working on it	working	working	✓
Recapturable	-	-	partly	fully	partly	party	fully










# Transcatheter Mitral Valves in Early Clinical Studies

	Study Type	Region	Status
<b>CardiAQ-Edwards</b>	Early Feasibility	US	Recruiting
<b>M3-Edwards</b>	Early Feasibility	North America	Recruiting
<b>Tendyne-Abbott Vasc</b>	Pivotal Trial	Global	Recruiting
<b>Intrepid-Medtronic</b>	Pivotal Trial	Global	Recruiting
<b>Tiara</b>	Early Feasibility	US, Canada, EU	Recruiting
<b>Caisson-LivaNova</b>	Early Feasibility	US	Recruiting



# Transcatheter Mitral Valves in Early Clinical Studies

	Both Transseptal and Transapical	Transapical Only			Transseptal Only
					
	CardiAQ- Edwards	Tendyne	Intrepid	Tiara	Caisson
Delivery System Size	33 Fr	32 Fr	35 Fr	32 Fr	31 Fr
Valve Size	40 mm	27 mm	27 mm	35, 40 mm	27 mm

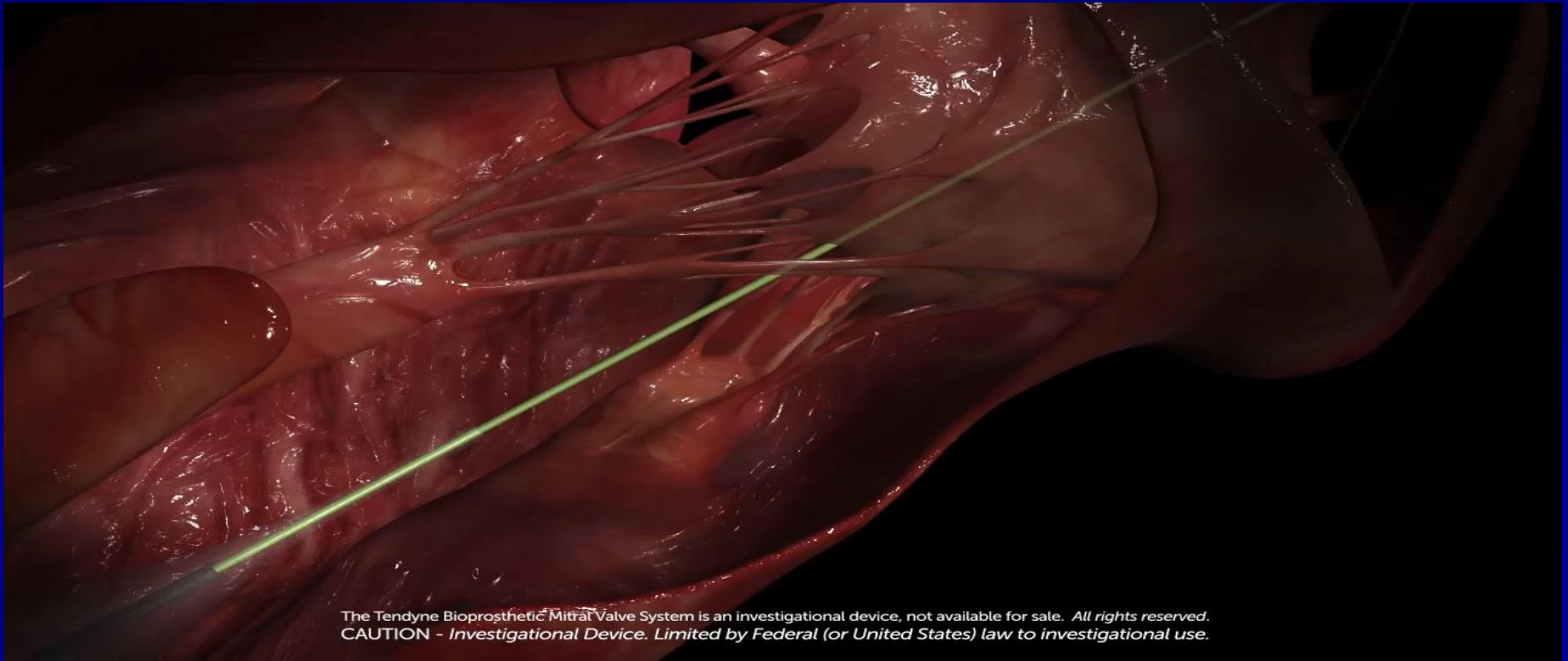


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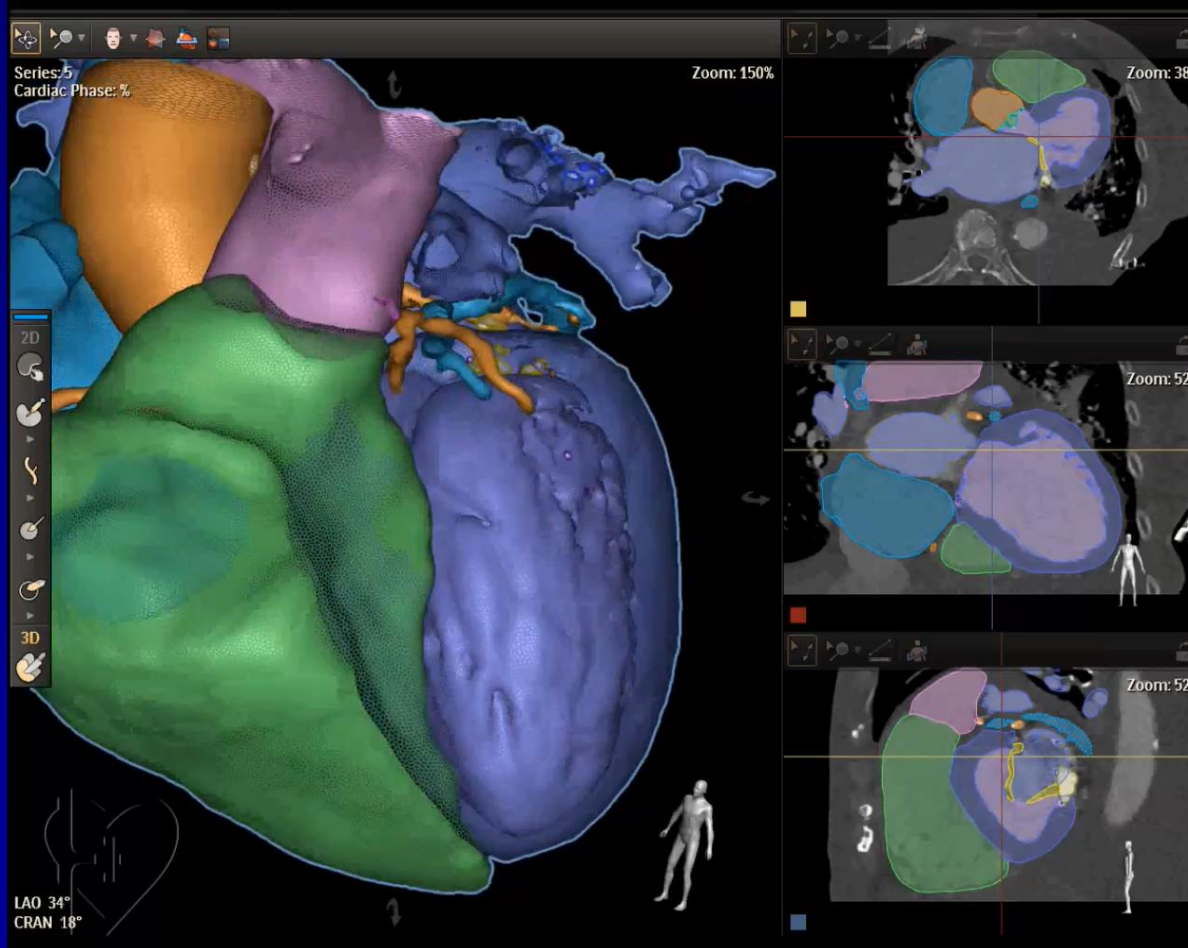
# Abbott Tendyne Implant Video



The Tendyne Bioprosthesis Mitral Valve System is an investigational device, not available for sale. All rights reserved.  
CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use.

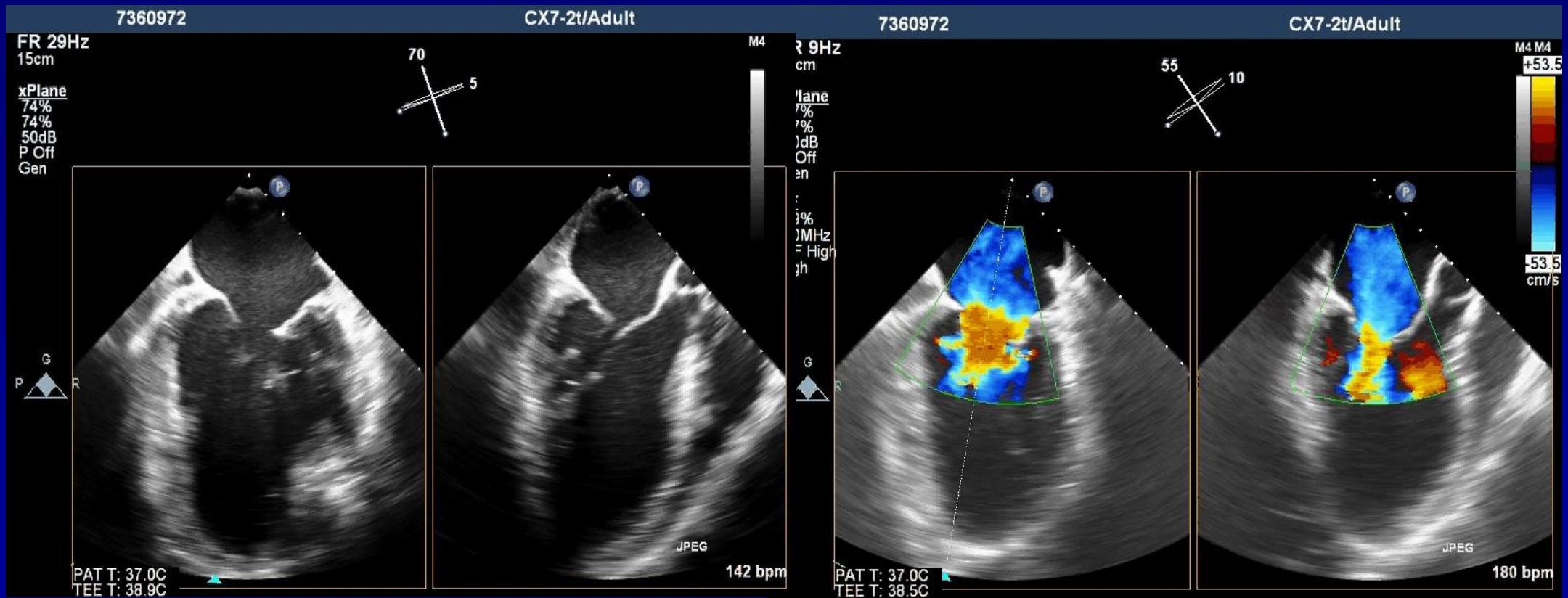


# Importance of accurate sizing



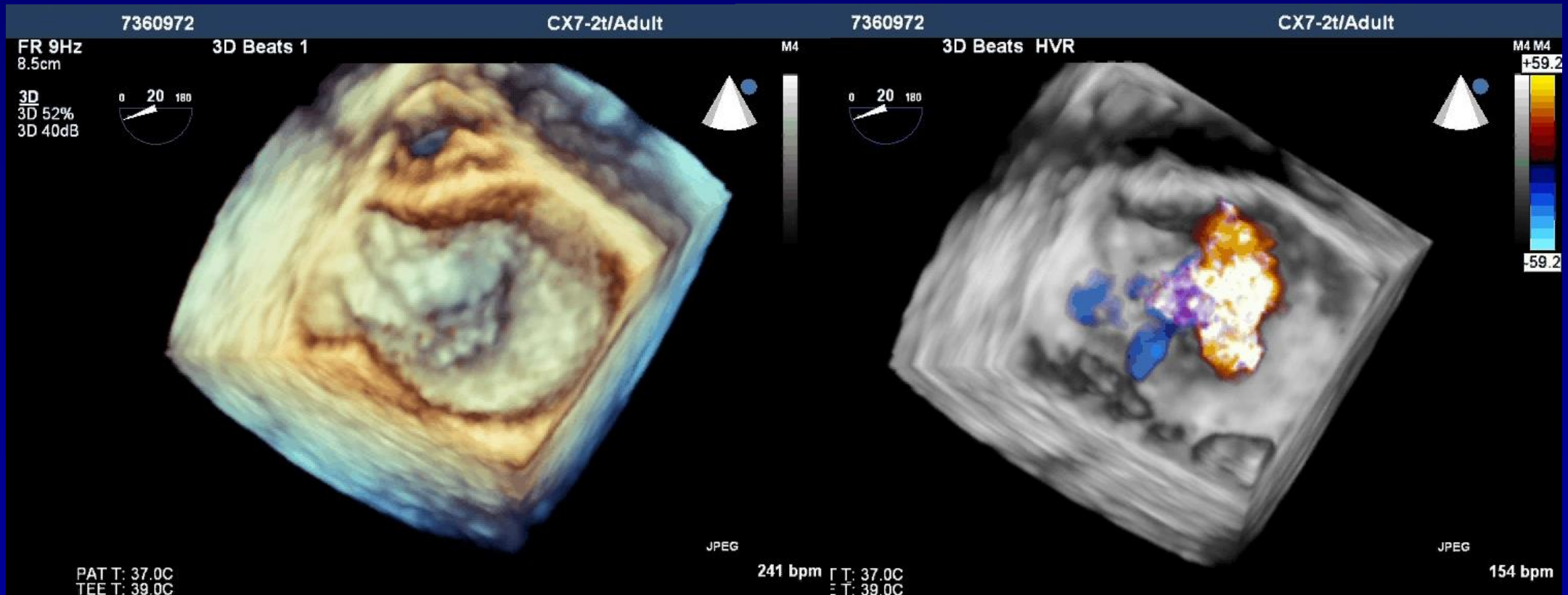


# Tendyne Case





# Tendyne Case



# Tendyne Case

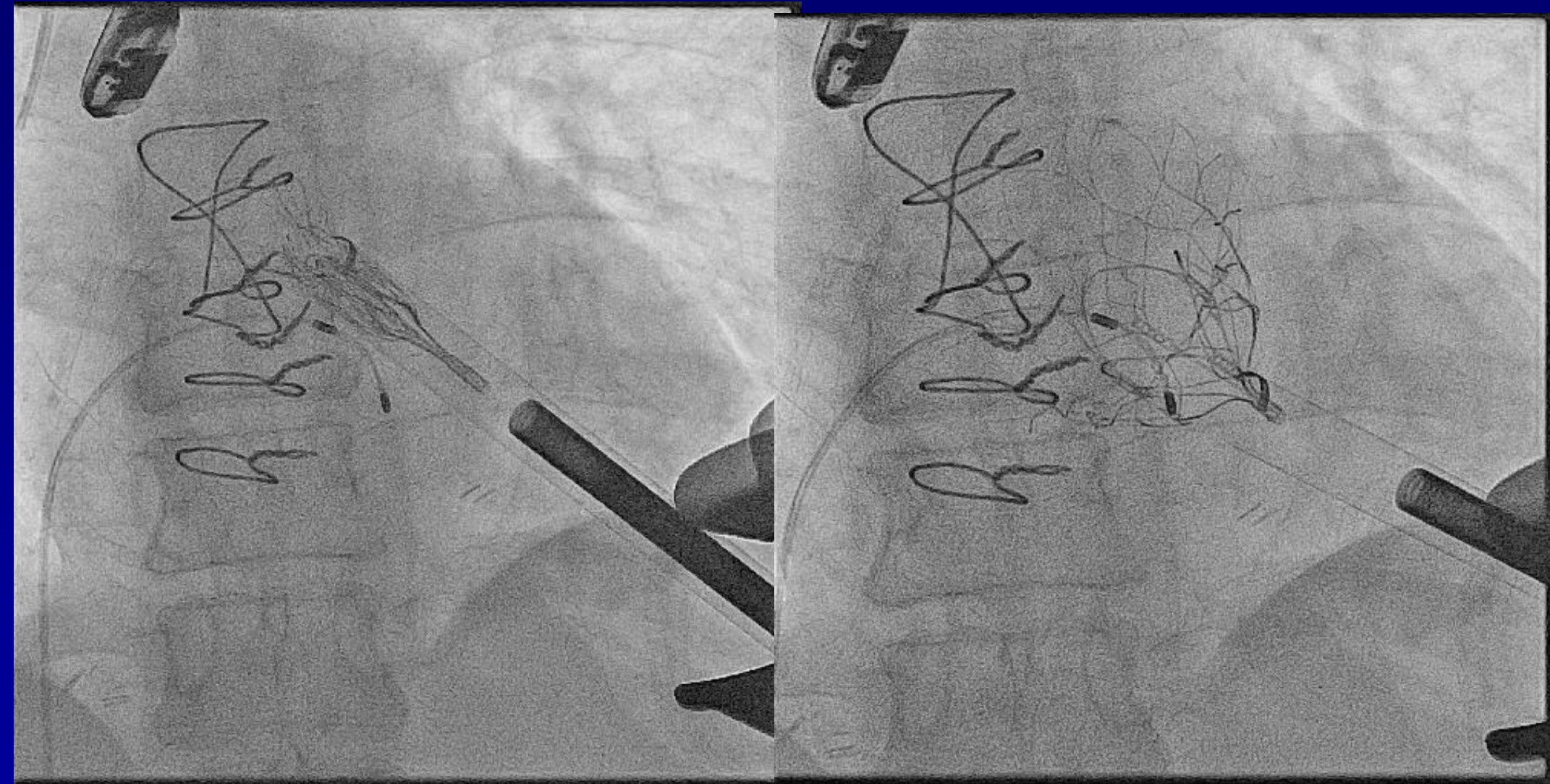


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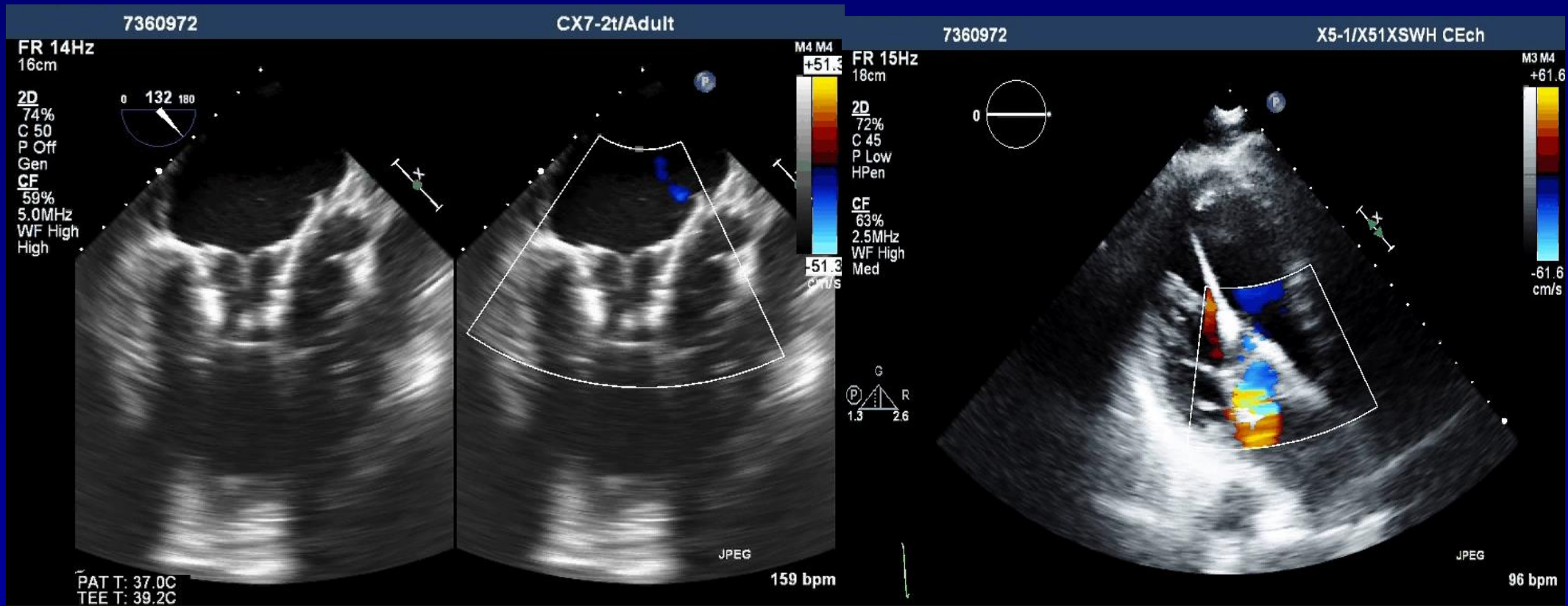


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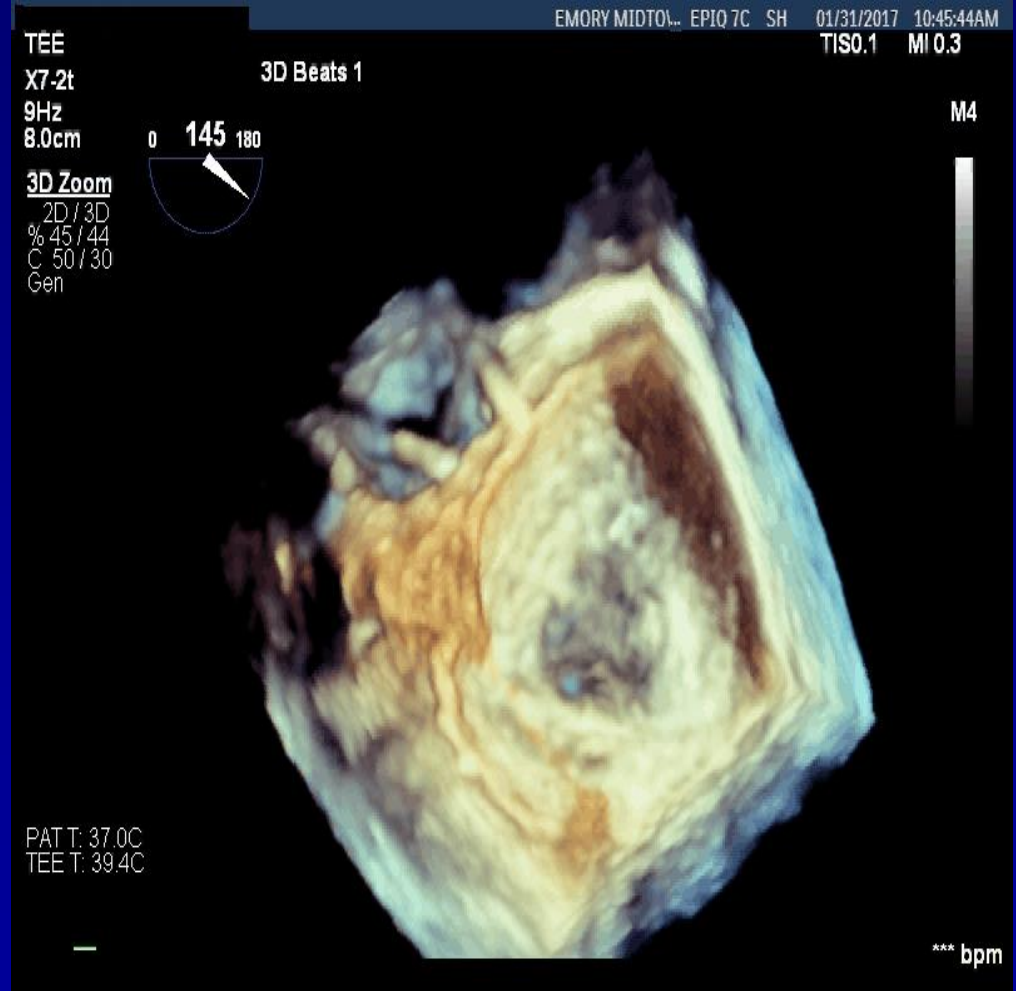
# Tendyne Case



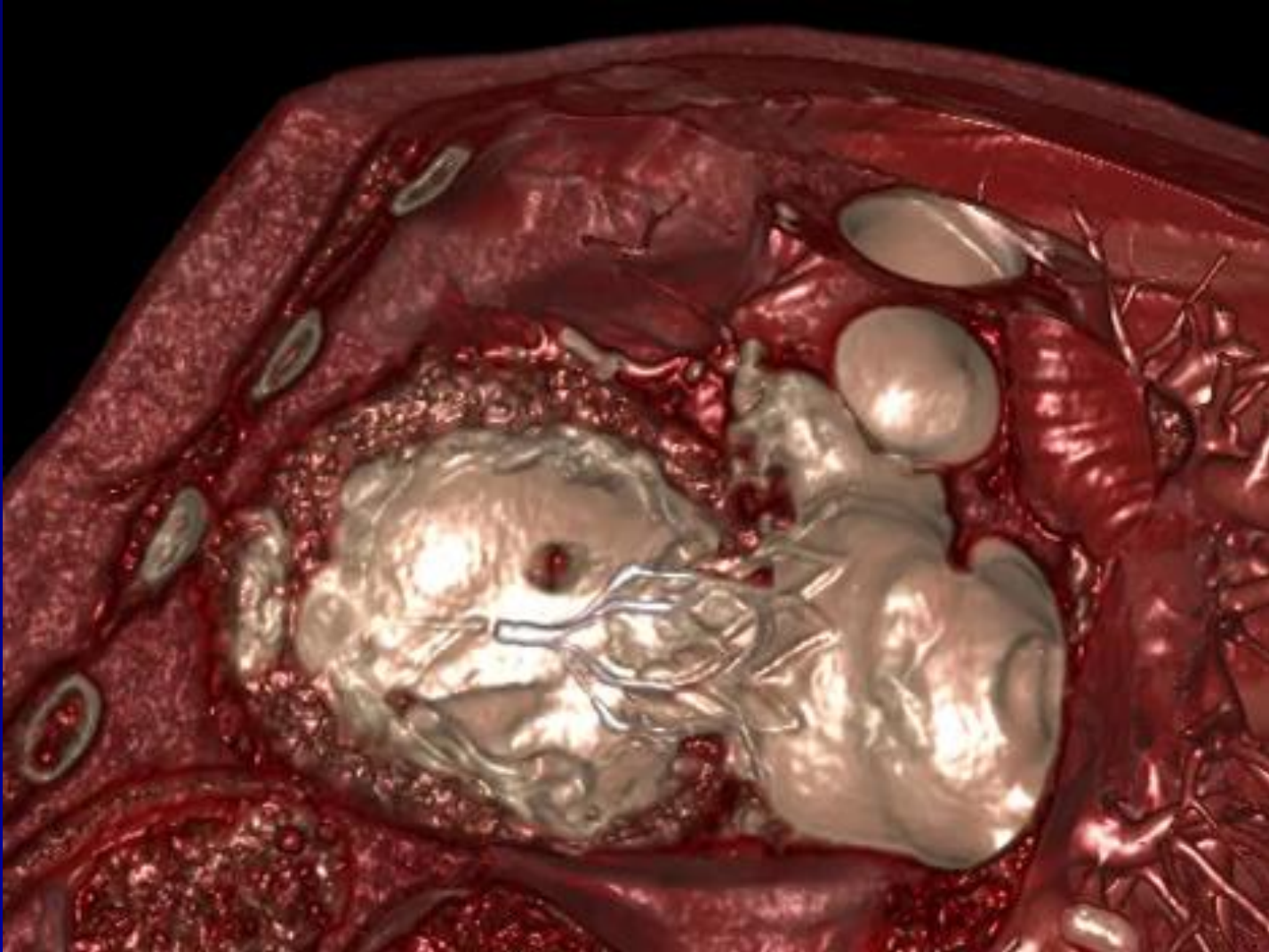




# Abbott Tendyne Implant Video



# Tendyne Valve



Courtesy of David Muller



# Abbott Tendyne Implant





# Tendyne TMVI Trials

## Global Feasibility Study (n=30)

- 8 sites, Australia, US and Norway

## Expanded Feasibility (CE Mark) Study (n=110)

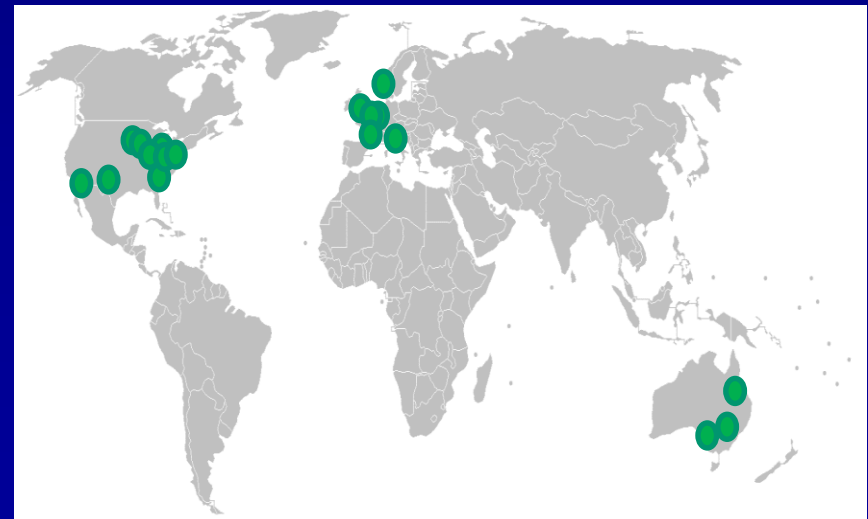
- Up to 25 centers (currently 23)
- Study expansion pending



## Compassionate Use (n=15)

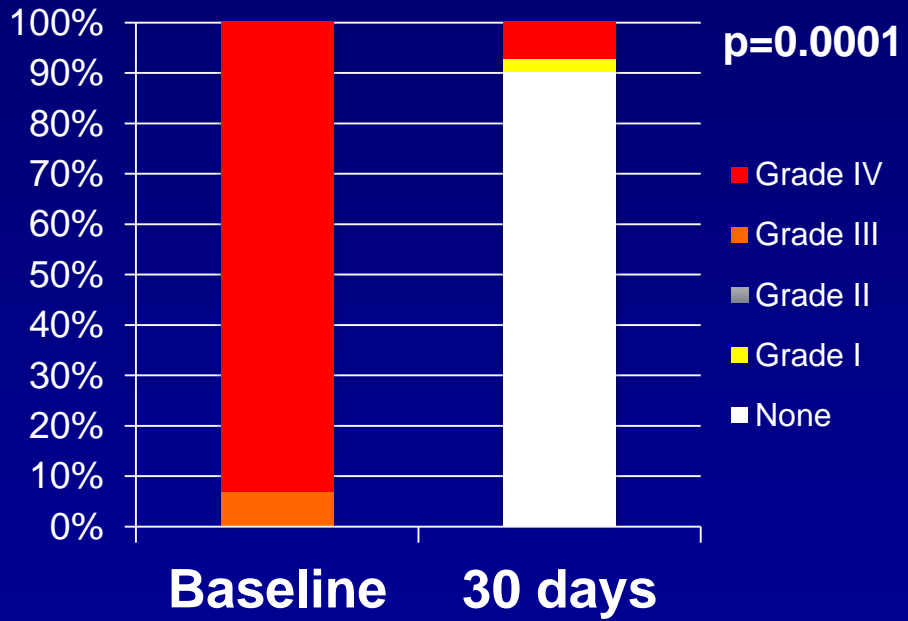
## Pivotal randomized trial

- Total >110 cases
- Longest follow-up 3.0 yrs

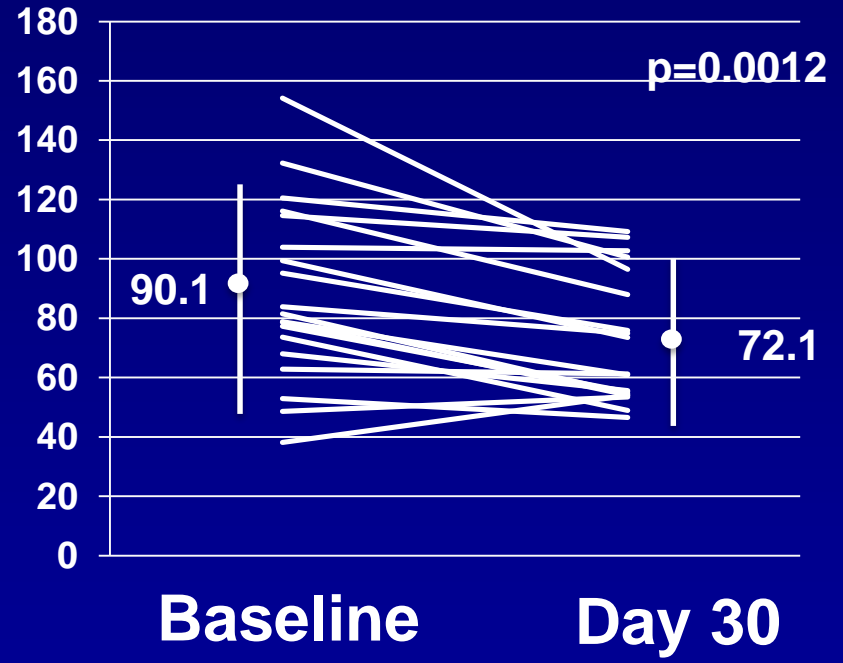


# 30 days post-TMVI (n=30)

## MR severity



## LV End-Diastolic Volume Index (mls/m<sup>2</sup>)



Mortality 3.3%  
Stroke/MI 0.0%



## Tendyne GFS: Patient Overview (n=75)

Characteristics	Primary (n=20)	Secondary (n=55)
Age	74.5±8.6	74.8±8.7
Female gender	9/20 (45%)	16/55 (29%)
NYHA III/IV	15/20 (75%)	33/54 (61%)
STS PROM >8	7/20 (35%)	20/55 (36%)
LVEF	52%	47%
Pulmonary HT	58%	38%
Atrial fibrillation	75%	60%



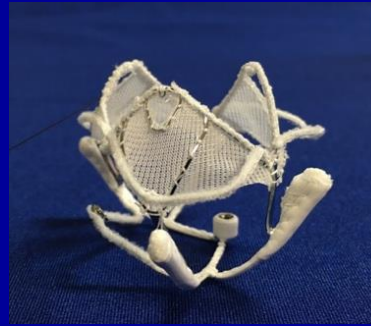
# Tendyne GFS: 30 day outcomes (n=75)

<b>Success</b>	80% (60/75)
<b>Non-success</b>	20% (15/75)
Mortality	6.7% (5/75)
<b>Implant not Successful</b>	4.0% (3/75)
LVOT obstruction	1.3% (1/75)
Valve not seated properly	1.3% (1/75)
Patient became unstable, procedure not completed, unplanned circulatory support	1.3% (1/75)
<b>Re-intervention</b>	2.6% (2/75)
Reposition device - resolve PVL	1.3% (1/75)
Bleeding with re-operation	1.3% (1/75)
<b>Valve performance</b>	6.7% (5/75)
Mitral valve gradient > 6 mmHg	5.3% (4/75)
Malpositioning/paravalvular leak	1.3% (1/75)

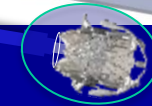
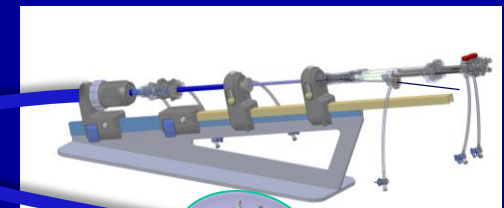
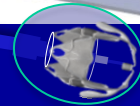
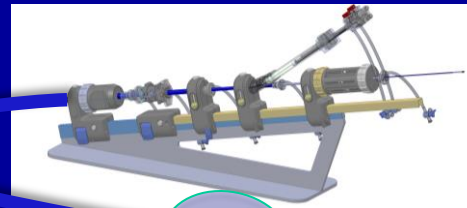
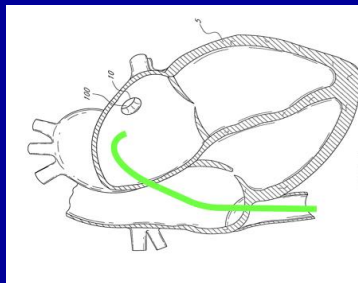
# Caisson TMVR System



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+



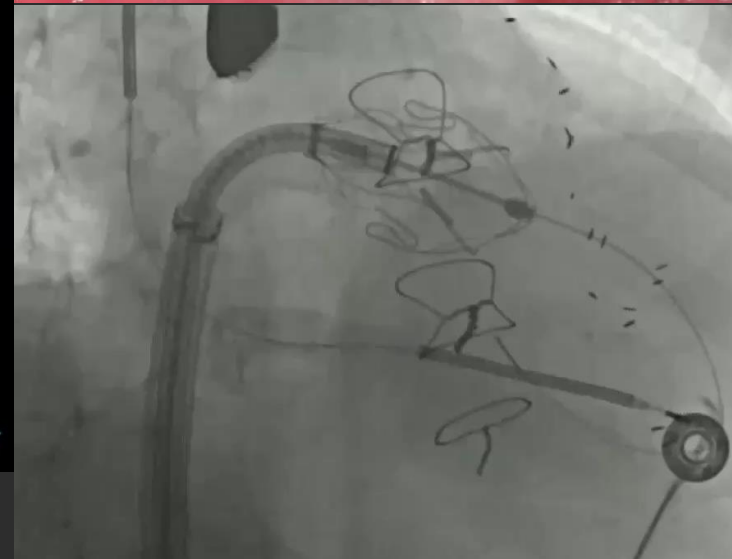
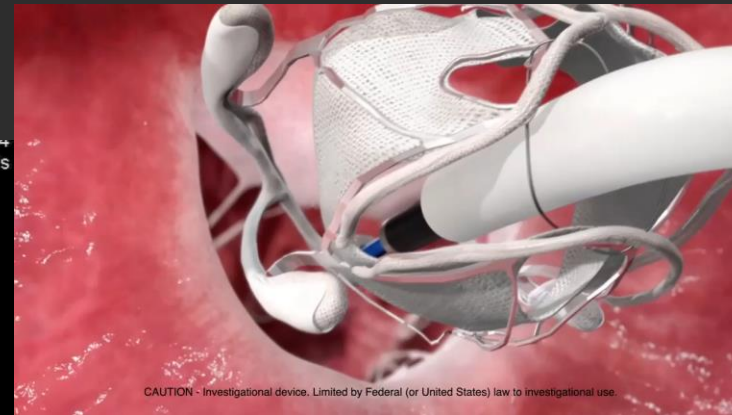
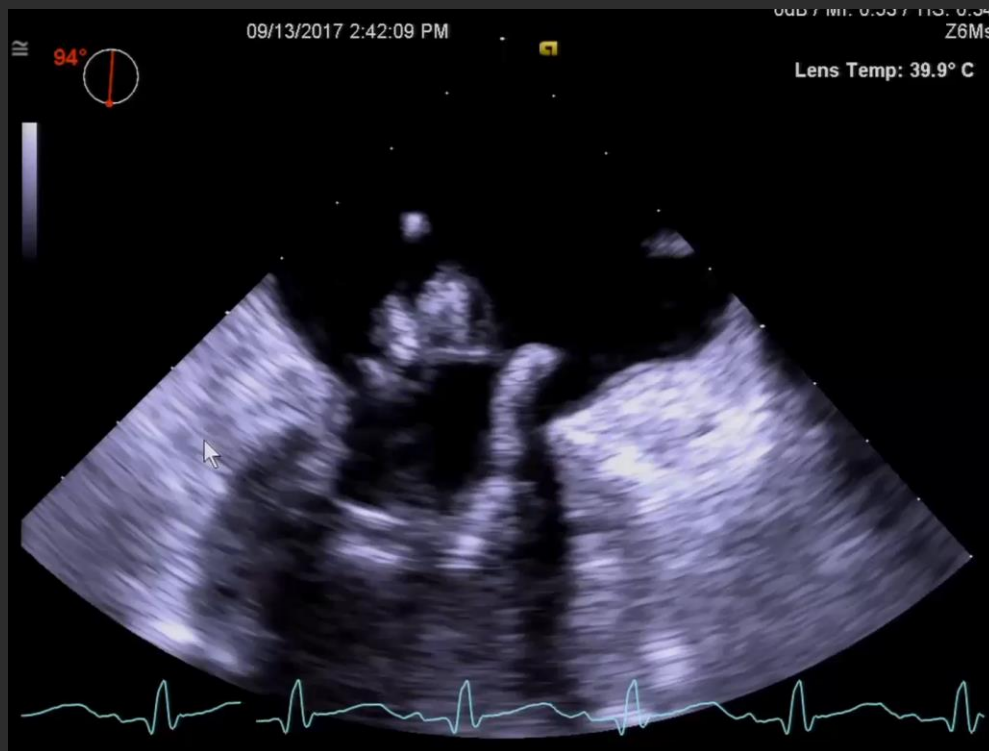
Transeptal  
System

Controlled  
Delivery

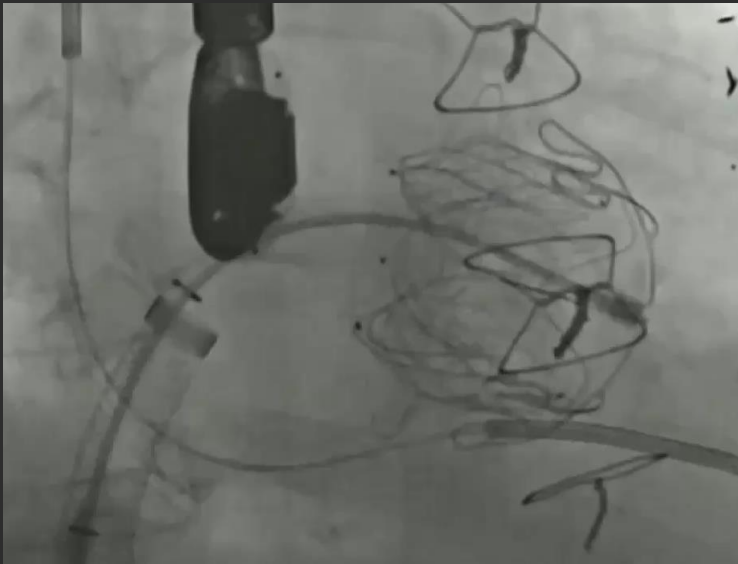
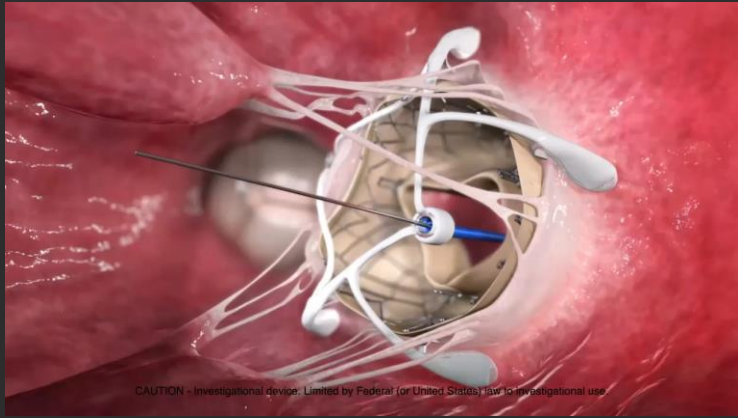
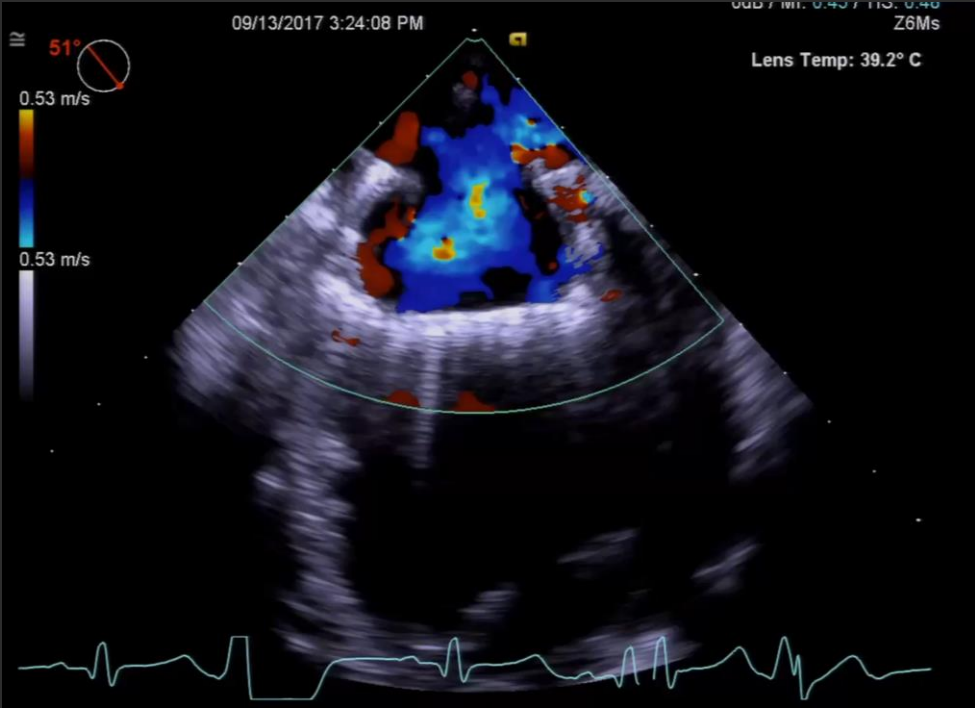
Repositionable/  
Retrievable



# Engaging the Annulus

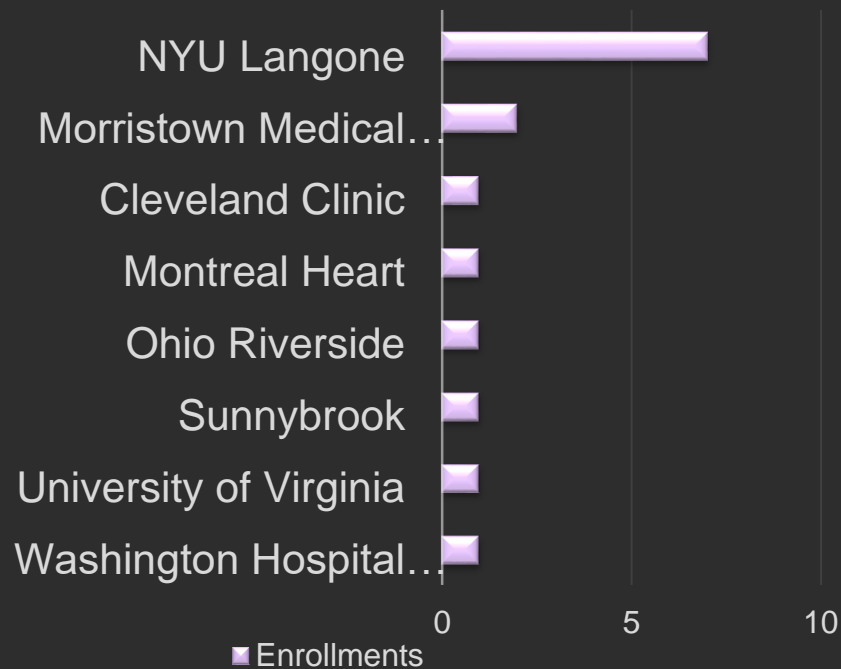


# Final Deployment



# Early Clinical Patient Summary Data

## Activated Sites


















## Patient Characteristics (n=15)

Gender ( <i>female</i> )	71%
LVEF % (mean/SD)	44.5 ± 12.5
STS predicted risk % (mean/SD)	8.1 ± 3.6
NYHA III-IV (% pt)	78.6%
eGFR (mL/min/1.73m <sup>2</sup> )	49.7 ± 16.3
BMI (kg/m <sup>2</sup> )	24.7 ± 4.2
MV Peak Velocity (m/s)	1.44 ± 0.29
MV Mean Gradient (mmHg)	3.13 ± 1.14
Categorization of MR	
Degenerative MR	14% (2)
Functional MR	57% (8)
Mixed MR	29% (4)

# Early Clinical Results

15 patients enrolled with 12 successful implants

Subject	Days Since Implant	MR Grade			Ejection Fraction %		NYHA	
		Baseline	Post Procedure <sup>(2)</sup>	Last Follow-up <sup>(2)</sup>	Baseline	Last Follow-up	Baseline	Last Follow-up
01 <sup>(1)</sup>	 28	4+	Trace	1+	32.6	N/A	III	N/A
02	 480	3+	0	0	57.3	60.2	III	I
03 <sup>(SAP)</sup>	 460	4+	0	0	28.0	N/A	III	N/A
04	 453	4+	0	0	57.9	61.6	II	I
05	 349	4+	Trace	0	58.9	46.7	III	I
06	 327	4+	Trace	0	47.6	26.8	IV	I
07 <sup>(3)</sup>	 20	3+	1+	N/A	56.0	56.6	III	N/A
08	 207	3+	1+	0	29.4	30.0	IV	I
09 <sup>(4)</sup>	 3	4+	Trace	N/A	36.4	N/A	III	N/A
10	 102	4+	Trace	0	46.0	40.0	II <sup>(5)</sup>	II
11	 89	3+	0	0	47.5	41.0	III	III
12	 47	4+	0	0	29.7	19.9	III	I

 In Follow-up  
 Converted to SMVR  
 Deceased

1: Early Death (Day 28) due to Sepsis  
 2: Grade inclusive of PVL  
 3: Conversion to SMVR due to excess PVL  
 4: Early Death (Day 3) following hypotension and PVL  
 5: Following medical management, NYHA III-IV at Screening

# Device Retrieval: Pt- 02-004

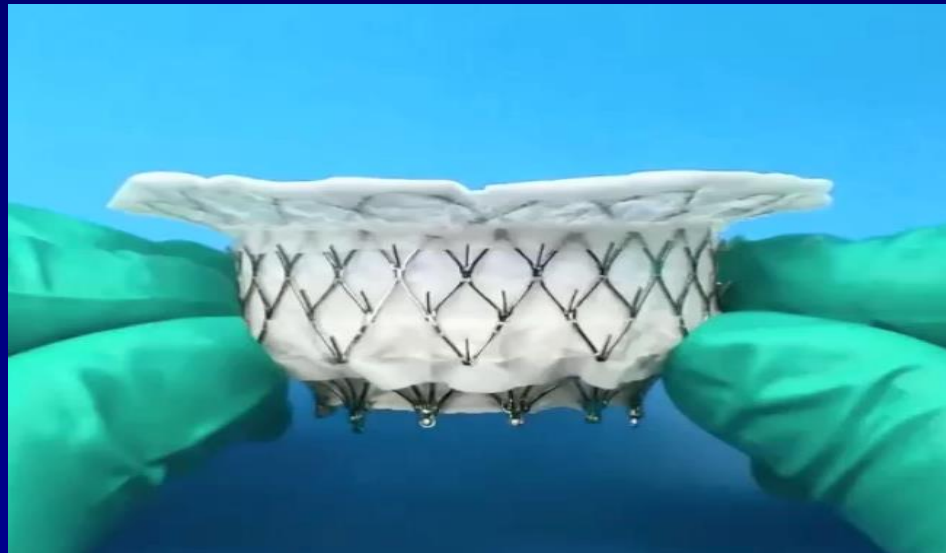
- Leaflet immobility and small orifice area led to inadequate Anchor stability
- Device fully retrieved. Patient received MitraClip treatment in same clinical setting.





# MEDTRONIC INTREPID™ TMVR

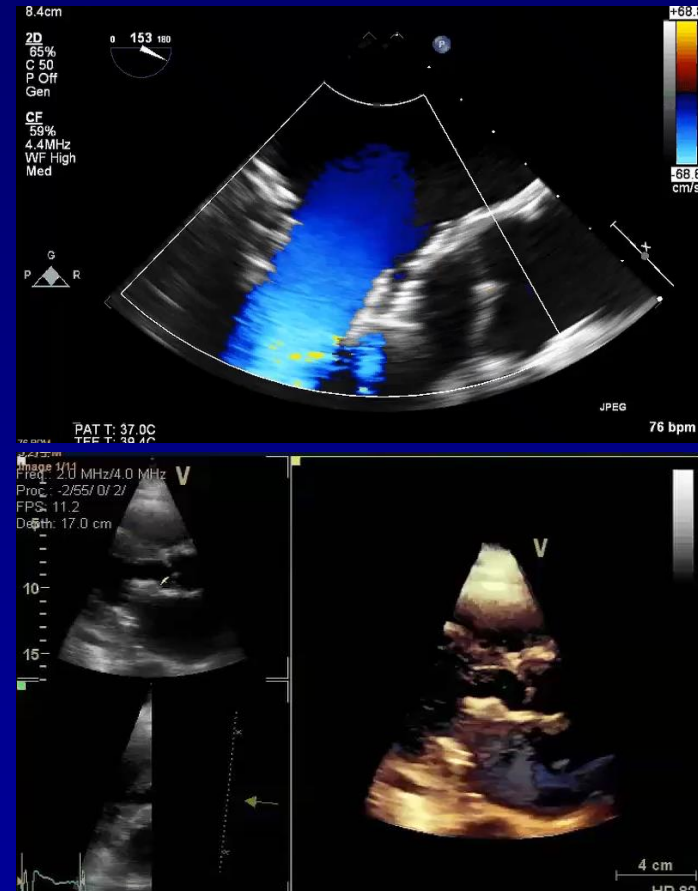
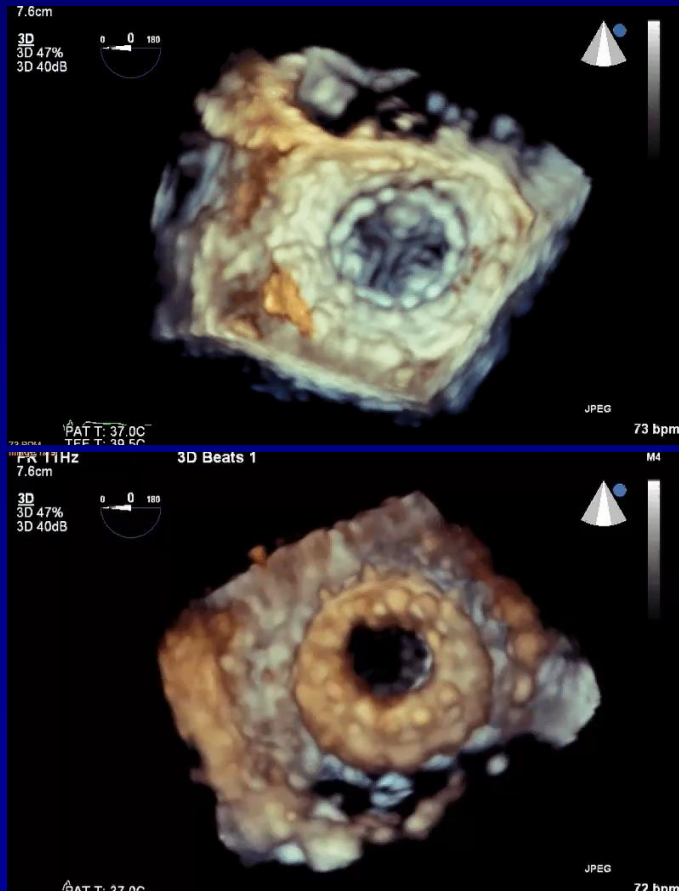
## DUAL STENT DESIGN



- Conformable Outer Stent engages the annulus and leaflets providing fixation & sealing while isolating the inner stent from the dynamic anatomy
- Circular Inner Stent houses a 27 mm tricuspid bovine pericardium valve
- Flexible Brim aids imaging during delivery & subsequent healing



# Medtronic intrepid™ TMVI



**CAUTION: INVESTIGATIONAL DEVICE. LIMITED BY FEDERAL LAW (USA) TO INVESTIGATIONAL USE.**



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# Results

## Pilot Study Clinical experience

### Procedural Outcomes (n=39)

Successful Deployment	36/38 <sup>1</sup>	
Apical Access Time (min)	31	(range: 17-53)
Deployment Time (min)	15	(range: 4-29)
Mean LVOT Gradient <sup>2</sup> (mmHg)	2	(range: 0-4)
Mean MV Gradient <sup>2</sup> (mmHg)	4	(range: 0-7)

1 - in one patient deployment was not attempted  
 2 - latest follow-up

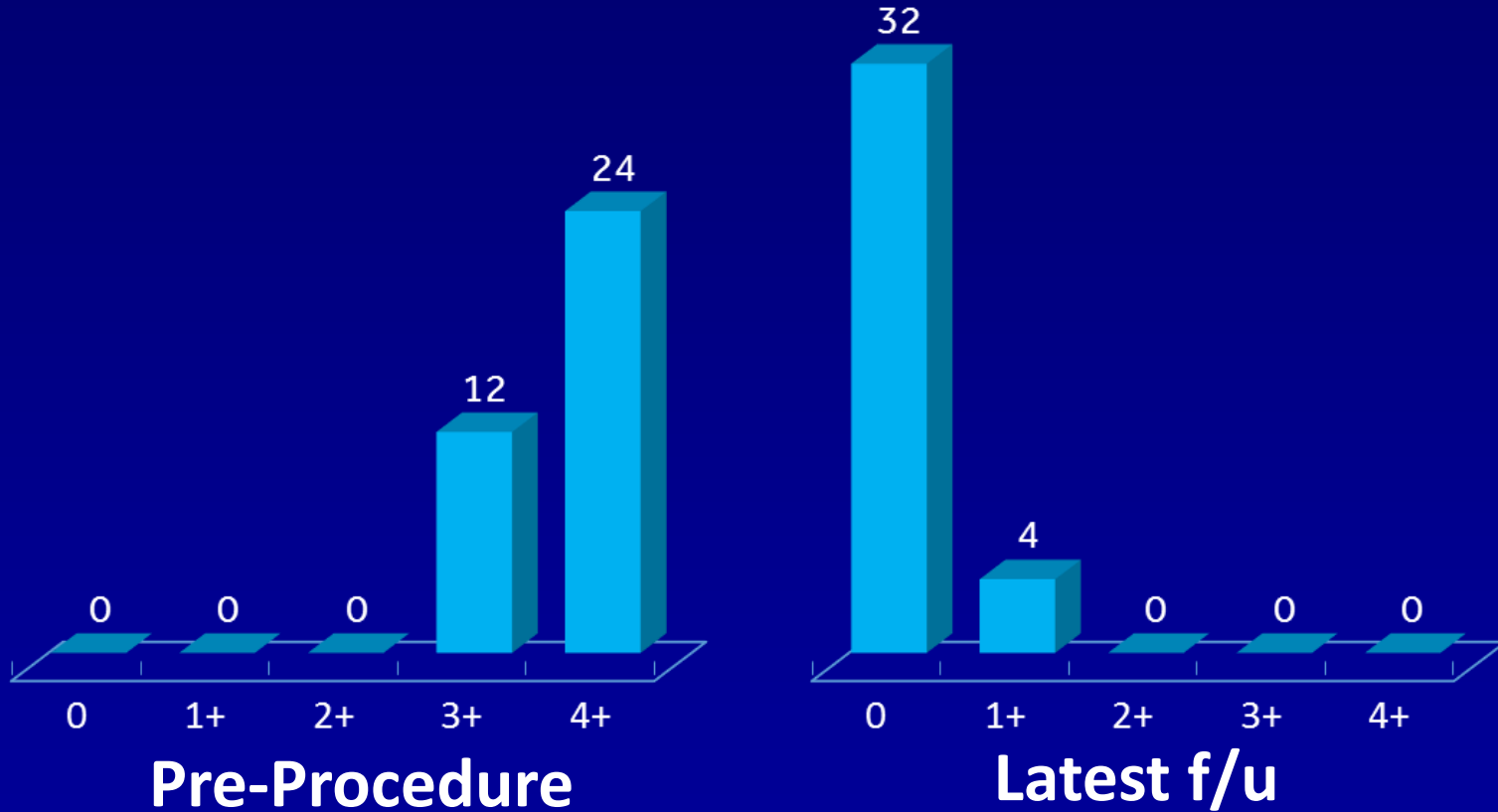




# Results

Pilot Study Clinical experience

## MR Grade



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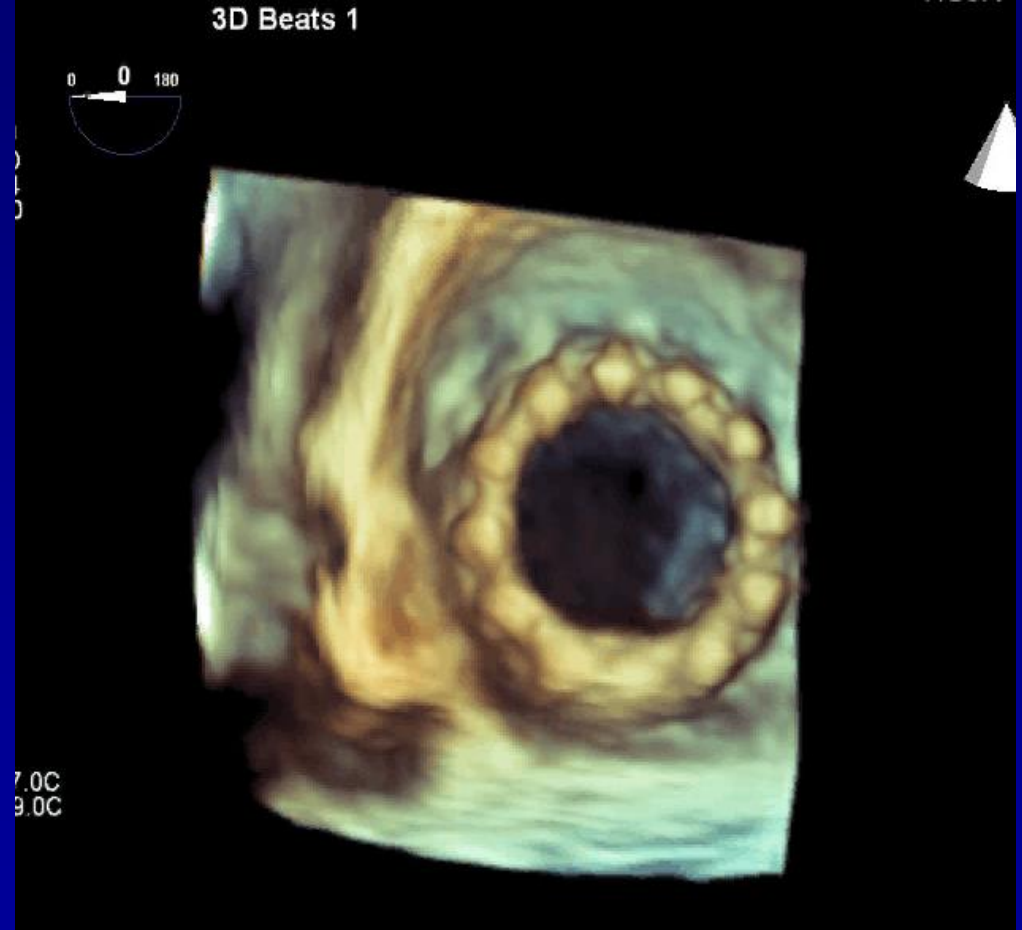
# Edwards-CardiAQ



- Porcine pericardium
- Nitinol self expanding
- 12 X2 opposing atrial and ventricular anchors
  - Delivery
  - Transapical
  - Transseptal



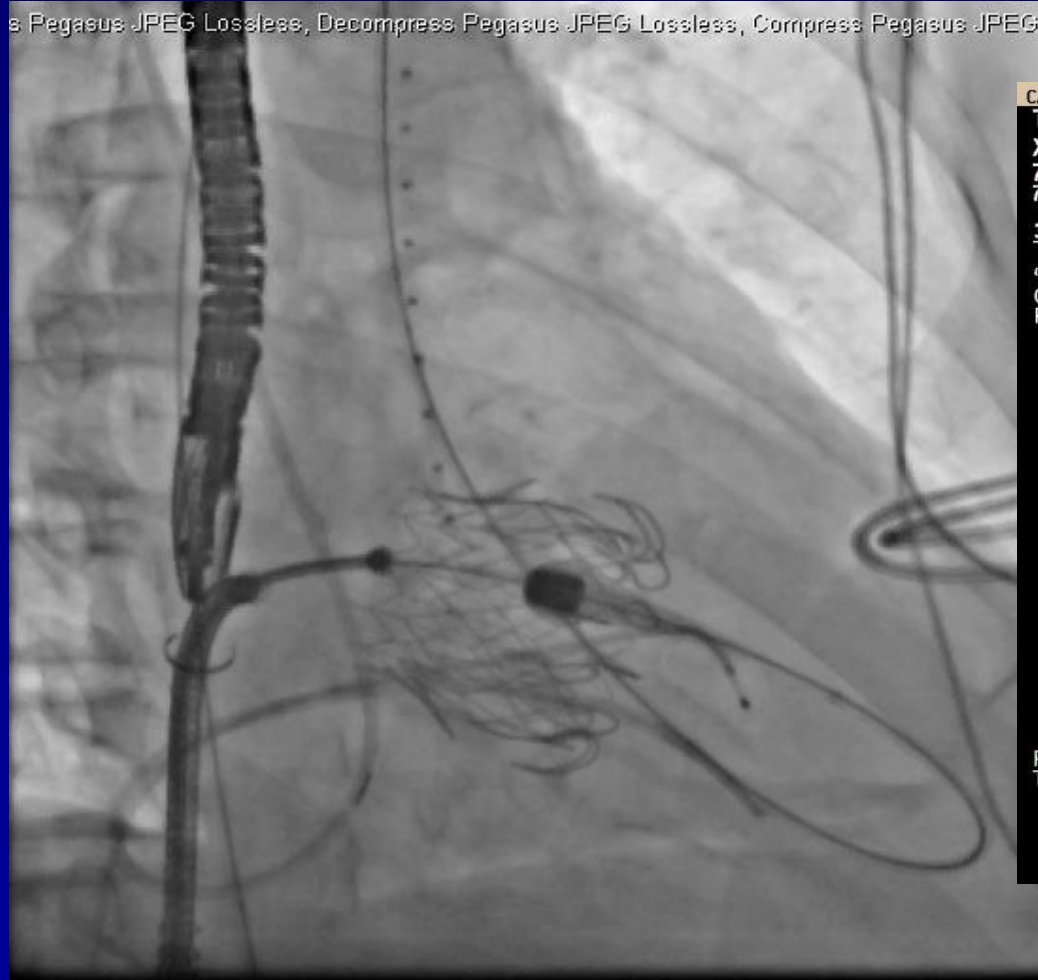
# CardiAQ-Edwards TMVR





# CardiAQ-Edwards TMVR: Transseptal Valve Release

s Pegasus JPEG Lossless, Decompress Pegasus JPEG Lossless, Compress Pegasus JPEG



CARDIAQ 03011020160923 EMORY HOSPIT... EPIQ 7C 09/23/2016 01:01:17PM  
 TIS0.0 MI 0.3

TEE  
 X7-2t  
 7Hz  
 7.4cm

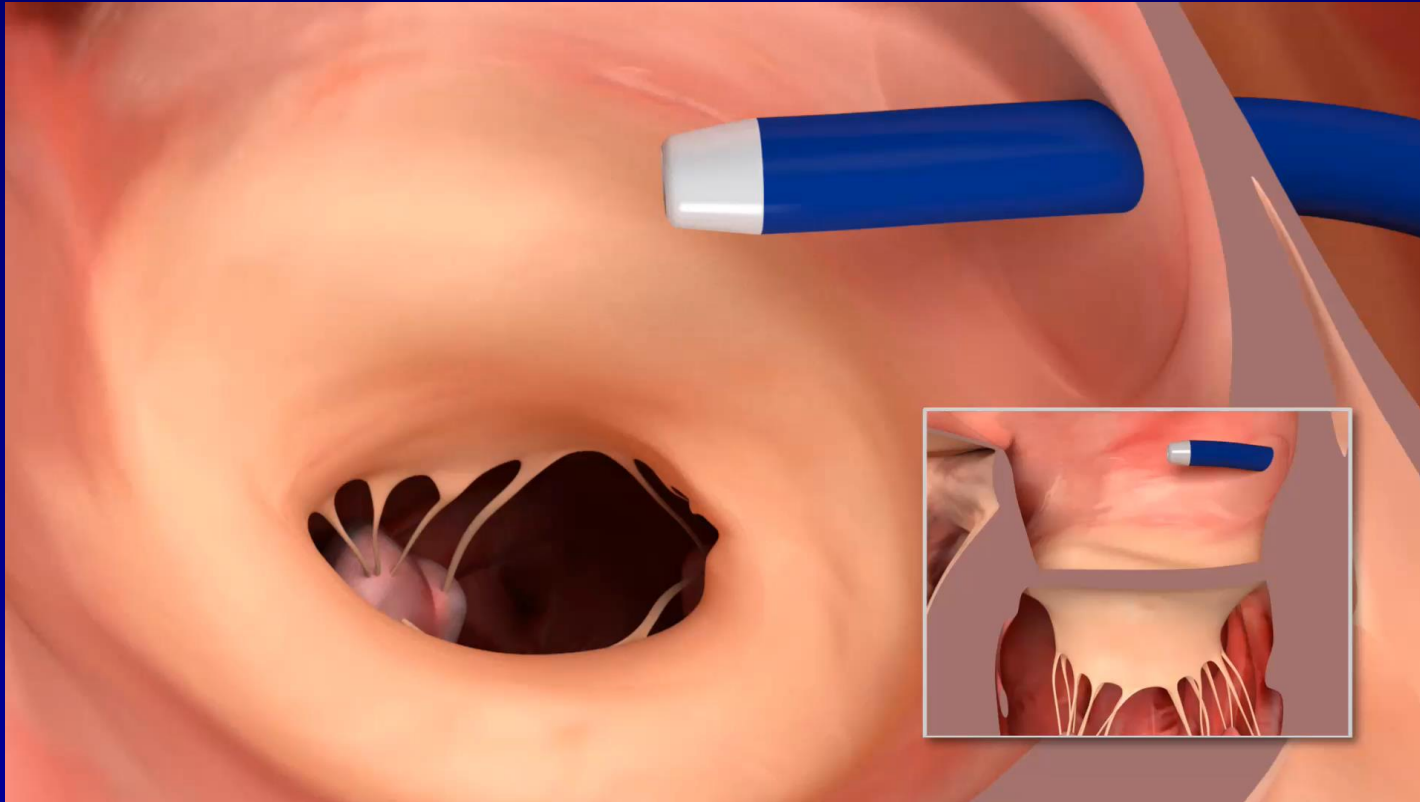
3D Beats 1

3D Zoom  
 2D / 3D  
 % 41 / 44  
 C 46 / 30  
 Pen

PAT T: 37.0C  
 TEE T: 38.5C

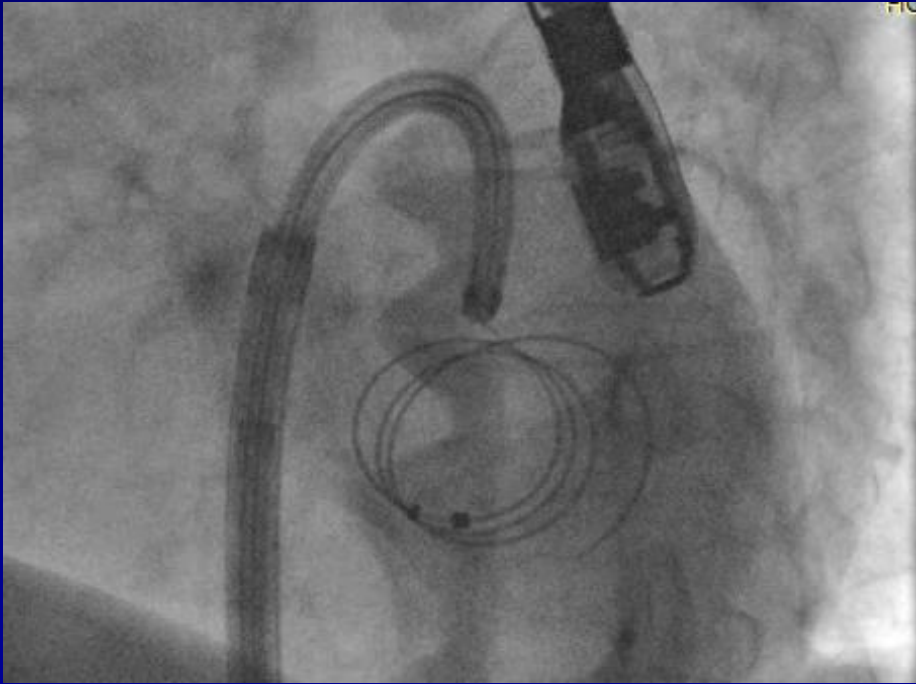
80 bpm

# SAPIEN M3 System Deployment

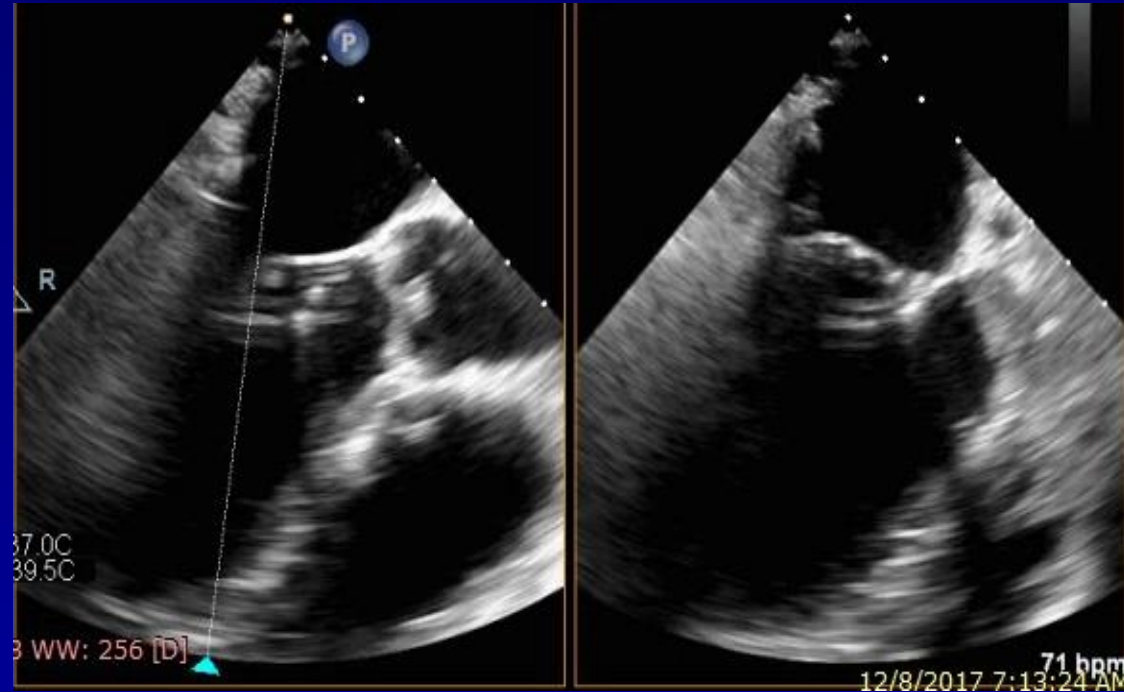


# SAPIEN M3 – Case Example

## Dock Deployment

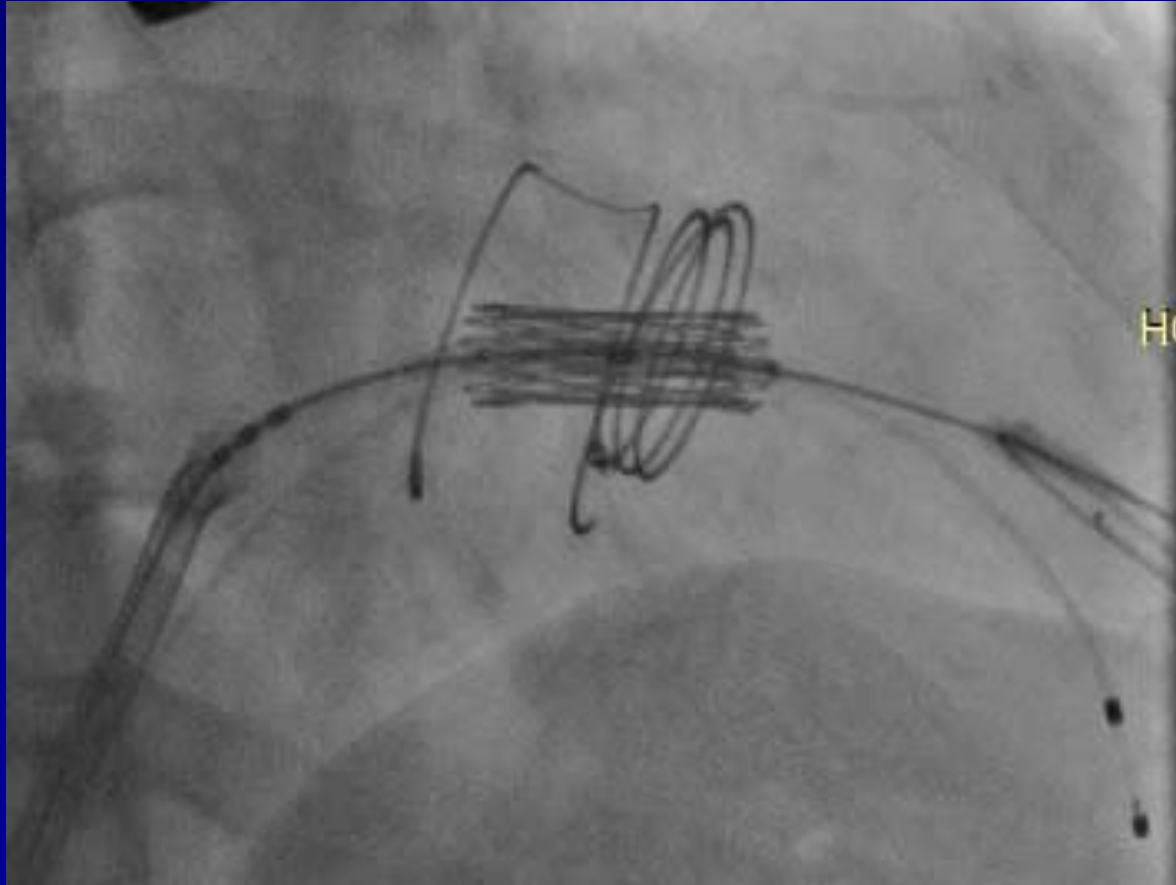


**Release of the atrial turn**



**Tee confirms dock encircling mitral leaflets**

# SAPIEN M3 – Case Example Valve Deployment



# SAPIEN M3 System Baseline Characteristics

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	<b>N=10</b>
Age, years, mean	74.1
Male, n	4
STS*, %	4.9
NYHA Class III or IV, n	10
Coronary Artery Disease, n	5
Prior CABG, n	4
eGFR $\leq$ 40, n	3
MR Grade $\geq$ 3, n	10
LVEF, mean, %	37.5

\*MV Replacement



# SAPIEN M3 System: Procedural Outcomes

Case #	Baseline LVEF (%)	Procedure Length (hrs)	Procedural MR Grade		Procedural Adverse Clinical Event	30 day MR Grade	30 day Clinical Status
			Pre	Post			
1	60	4	Severe	Trace	None	Severe <sup>(1)</sup>	Alive
2	33	7.3 <sup>(2)</sup>	Moderate-Severe	Mild	Chordal Rupture	Trace	Alive
3	35	2.5	Severe	Mild	None	None	Alive
4	30	2	Moderate-Severe	None	None	None	Alive
5	32	2.1	Severe	None	None	None	Alive
6	42	1.8	Severe	Trace	None	Trace	Alive
7	32	3.7	Severe	Mild	None	Trace	Alive
8	30	3.8	Severe	Mild	None	Trace	Alive
9	41	2.5	Moderate-Severe	None	None	None	Alive
10	40	1.3	Moderate-Severe	None	None	Mild	Alive

<sup>1</sup>PVL was closed with a plug which reduced post-30 day MR to 2+

<sup>2</sup>Chordal rupture during dock deployment resulted in severe PVL; closed intra-procedurally with plugx2; stroke (POD 02)

# SAPIEN M3 System

## First 10 Cases - Data Summary

	<b>N=10</b>
<b>Technical Success*</b>	9
Alive	10
Successful access/Delivery	10
Deployment	10
Freedom from Re-intervention	9 <sup>(1)</sup>

<b>Clinical Outcomes at 30 days*</b>	<b>N=10</b>
All-cause Mortality	0
All Stroke	1 <sup>(1)</sup>
Rehospitalization (device/procedure related)	0
Hemolysis	0
LVOT Obstruction	0

**There was no Conversion to Surgery, Device Embolization, Device Migration or Implantation of more than one valve.**

**\*Site reported**

<sup>1</sup>Case #2: Chordal rupture during dock deployment resulted in severe PVL; closed intra-procedurally with plugx2; stroke (POD 02)



# TMVR - Interventional Perspectives

## ANATOMY Summary

- “Hostile” anatomy resulted in a variety of valve designs secondary to the excessive screen failures in the early TMVR experiences.
- Major culprits are:
  - annulus size (too large or too small)
  - neo-LVOT size (too small)
  - MAC (severity, location and interaction with leaflets),
  - other considerations (e.g. severe TR with RV dysfunction).
- No design thus far has been seen as a clear winner



# Conclusions

- **While surgical results with primary MR are excellent, much is to be desired for functional MR**
- **The era of transcatheter valve technology will be a great complement to the management of MR**
- **The heart team is required to decide the most appropriate therapy for this complex patients**
- **Patients will benefit from valve centers that are poised to offer both surgical and transcatheter options**



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# Thanks

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