Update on Transcatheter Mitral Valve Repair and Replacment

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STS Cartagena Meeting
September, 2017

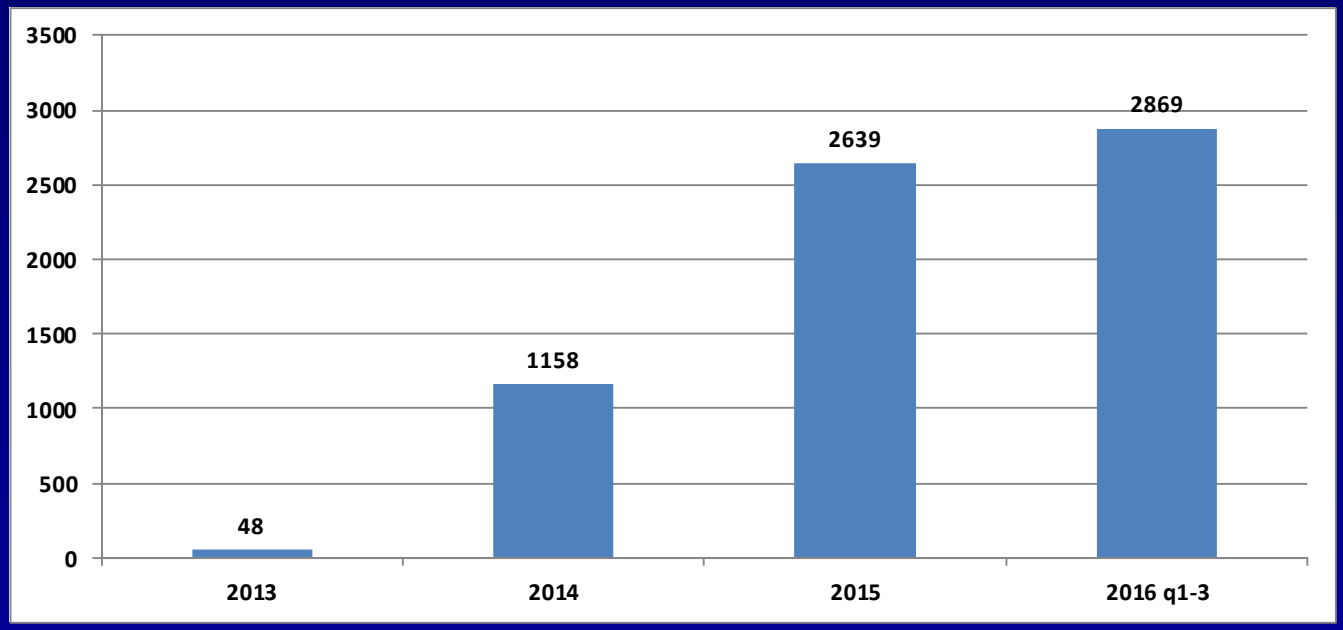
Disclosures

- **Abbott Medical/St. Jude Medical**
  - **Structural Heart Advisory board**
  - **Executive Committee: Portico trial**
- **Boston Scientific**
  - **Advisory Board, Executive Committee (Lotus Valve Trial)**
- **Cryolife**
  - **Advisor**
- **Edwards Lifesciences**
  - **National Co-PI: PARTNER 2 (SAPIEN 3 Trial)**
  - **Executive Committee: PARTNER 3 trial**
  - **Advisor**
- **Gore**
  - **Advisor**
- **Jenavalve**
  - **National Co-PI**

Transcatheter Mitral Valve Repair Techniques

- Mitraclip (FDA approved for Degenerative MR)
- Harpoon Device (Europe only)
- NeoChord Device (CE Mark, US Trials)
- Edwards PASCAL Mitral Repair System (EFS)

Commercial Mitral Leaflet Procedures Submitted to the TVT Registry



U.S. commercial use approved DMR in patients at prohibitive risk for surgery.

Does not include investigative cases (i.e. COAPT for patients with FMR).

U.S. catching up with >30K cases performed worldwide.

Source: STS/ACC TVT Registry Database as of Jan 17, 2017

Total Submitted MitraClip Cases = 6,714

Mitral Valve Disease Etiology

Etiology - % of pts with:	2014 *(n=1,023)*	2015 *(n=3,362)*
Degenerative Mitral Regurgitation (DMR) only	79.7%	75.5%
Functional Mitral Regurgitation (FMR) only	10.0%	8.8%
Mixed (both FMR and DMR)	6.2%	10.1%
Neither DMR and FMR	4.2%	5.6%

Source: STS/ACC TVT Registry Data Mart 3,362 pt records from 2014-15, as of 4-24-16

Leaflet Clip Procedures

At discharge	2014 *(n=1,023)*	2015 *(n=3,362)*
Mitral Regurgitation (<=2+)	92.0%	92.0%
MV Mean Gradient <=8 mmHg	92.3%	93.8%
Single Leaflet Device Attachment	1.2%	1.6%
MV Re-intervention	0.4%	0.9%
ASD requiring closure	1.6%	1.6%

Source: STS/ACC TVT Registry Data Mart 3,362 pt records from 2014-15, as of 4-24-16

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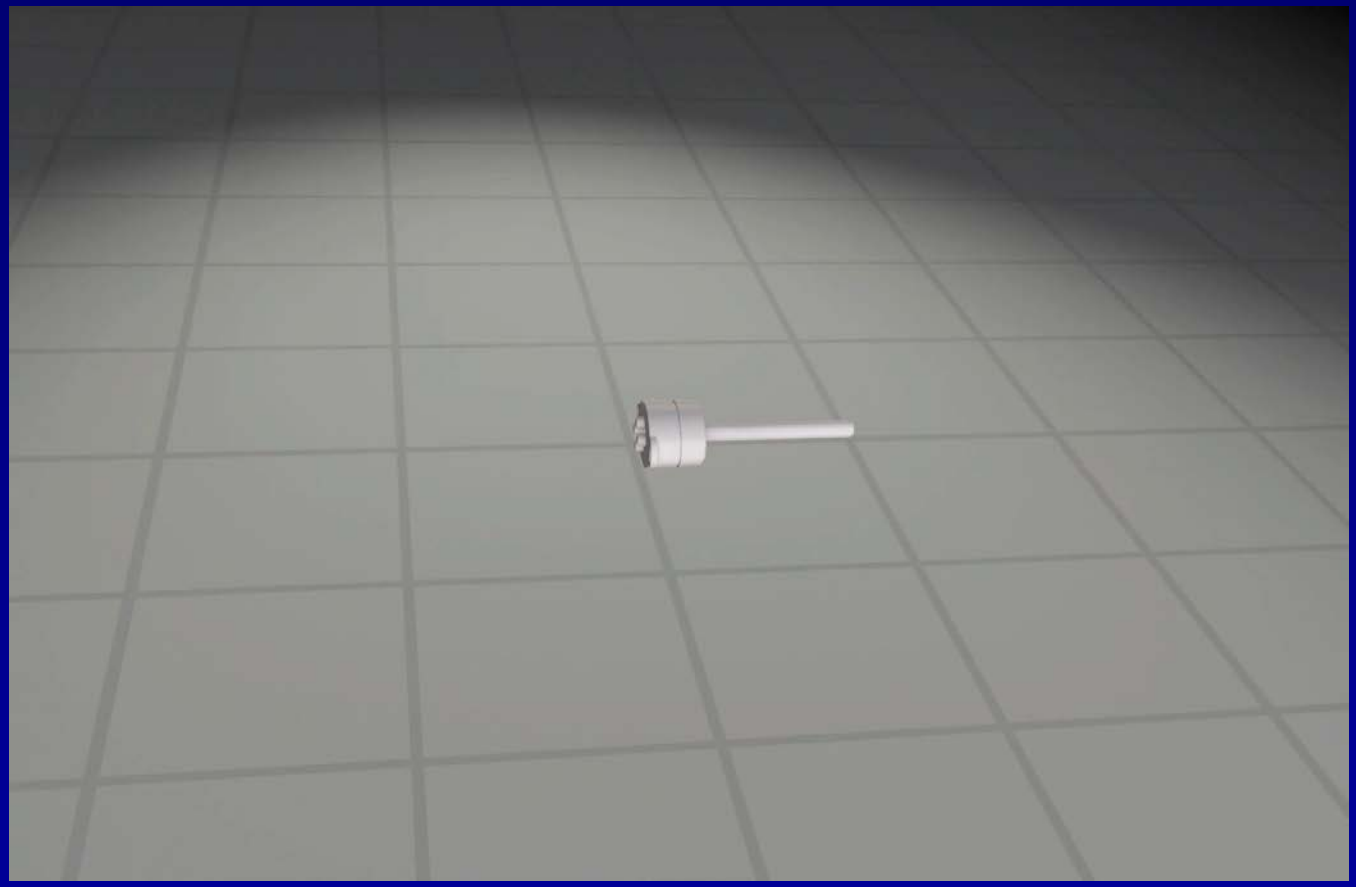
Harpoon Procedure



- Simplified off-pump repair of degenerative MR
- Image-guided placement & anchoring of ePTFE cords
- Real-time titration of cords on the beating heart to maximize coaptation

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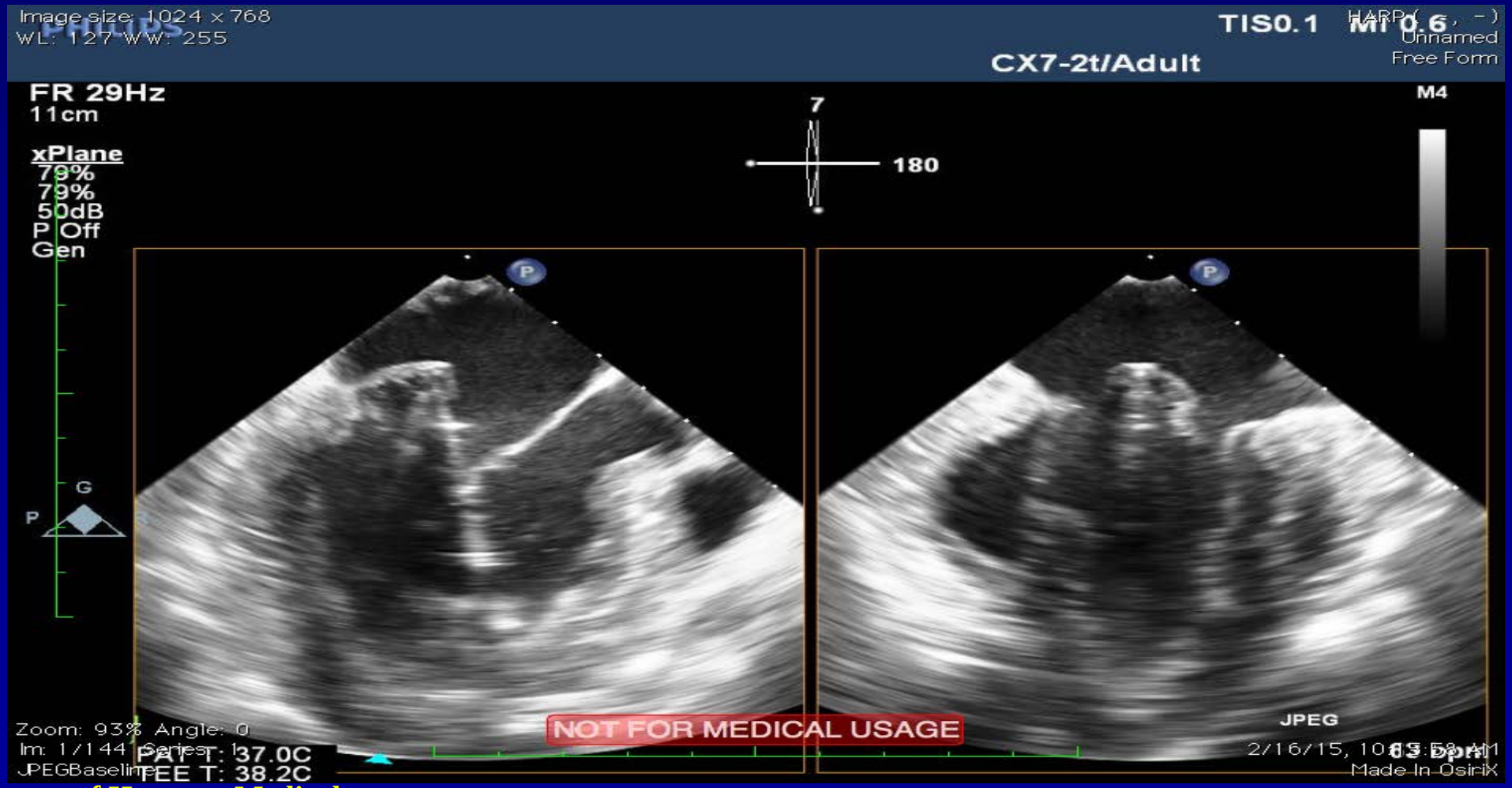
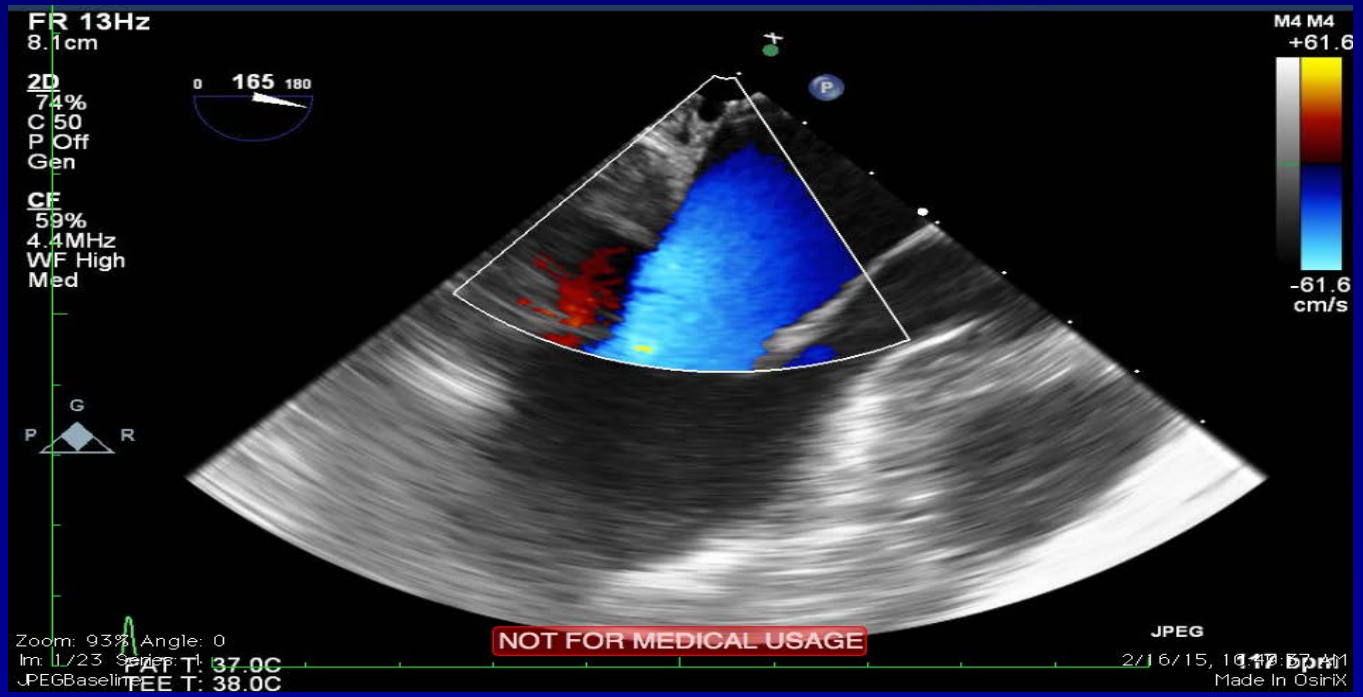
The Harpoon Device



Courtesy of Harpoon Medical

Patient # 1: Harpoon Device

Intraprocedural TEE (ePTFE neochords tightened)



MR Grade: TRACE

Courtesy of Harpoon Medical

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Excellent Safety Profile

- **No Mortality**
- **No Stroke**
- **No Renal Failure**
- **No Myocardial Infusion**
- **No Blood Transfusion**
- **No New Onset Post-Op AFib**

Adverse Events

- **Two Reoperations for Delayed Tamponade (POD 5, 13)**
- **Two Reoperations for Recurrent MR (POD 72, 231)**
  - **One patient ePTFE cord untied at apical pledget**
  - **One patient native anterior cord ruptured**
  - **Both patients received successful re-operations**

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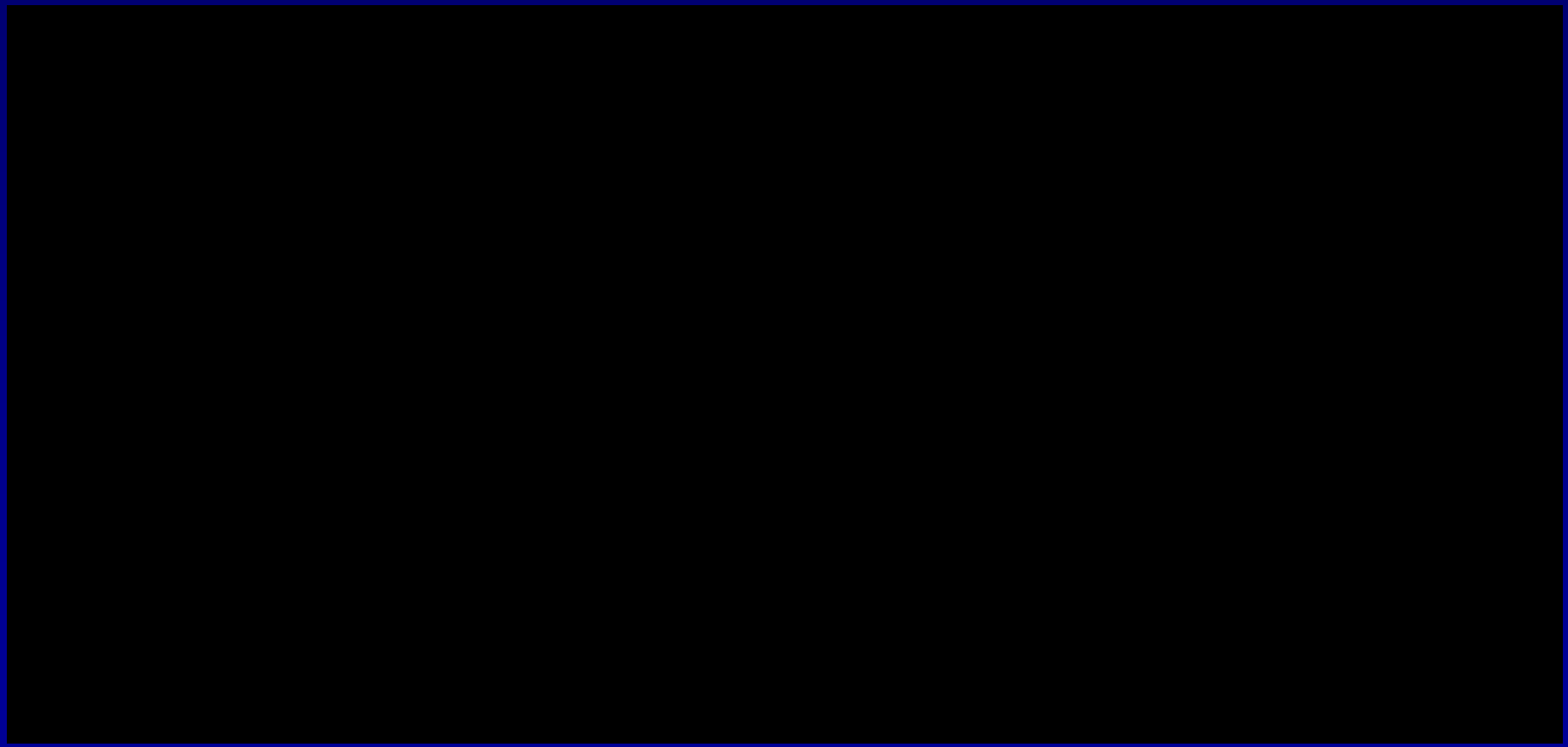
Neochord



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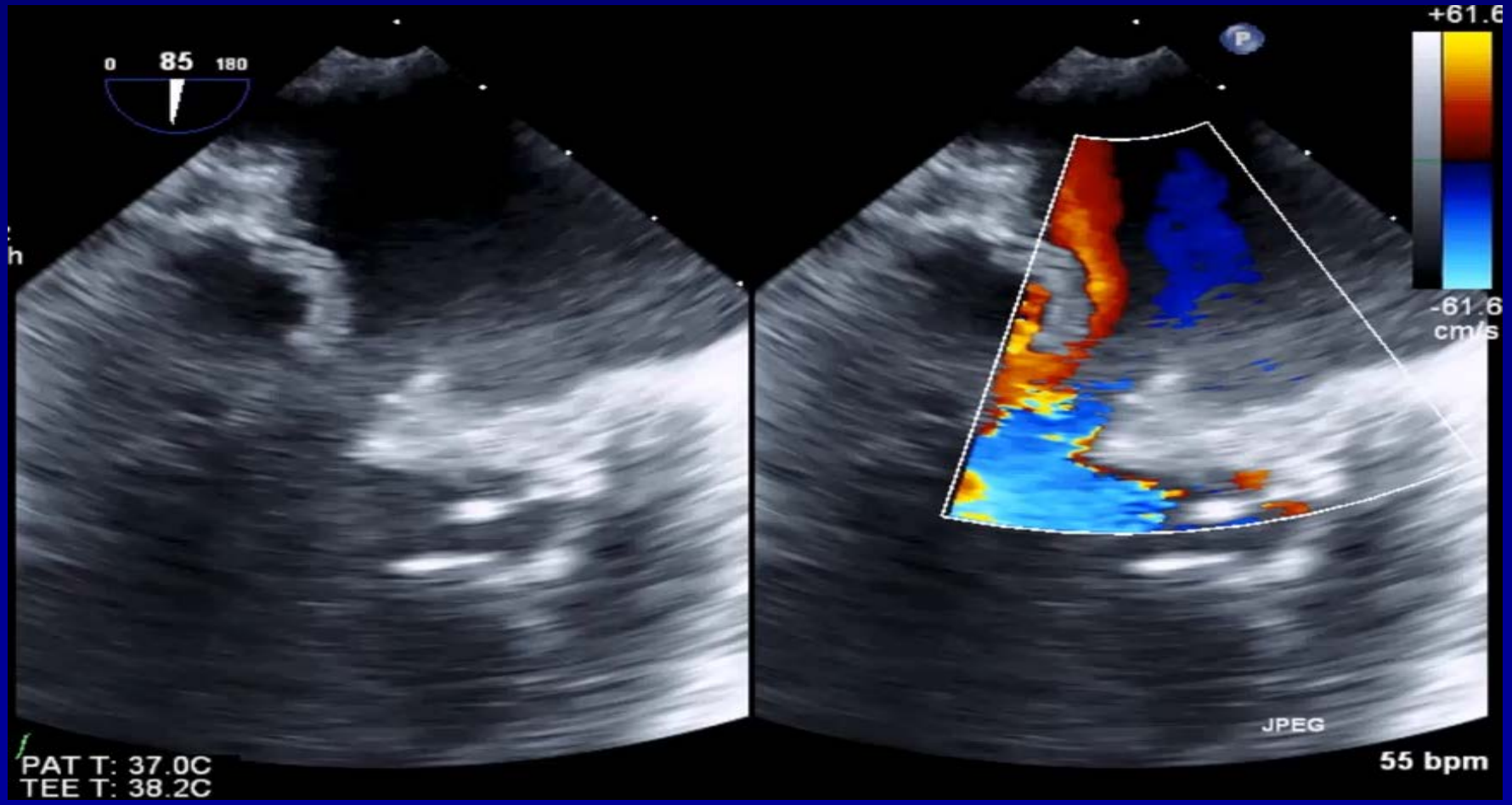
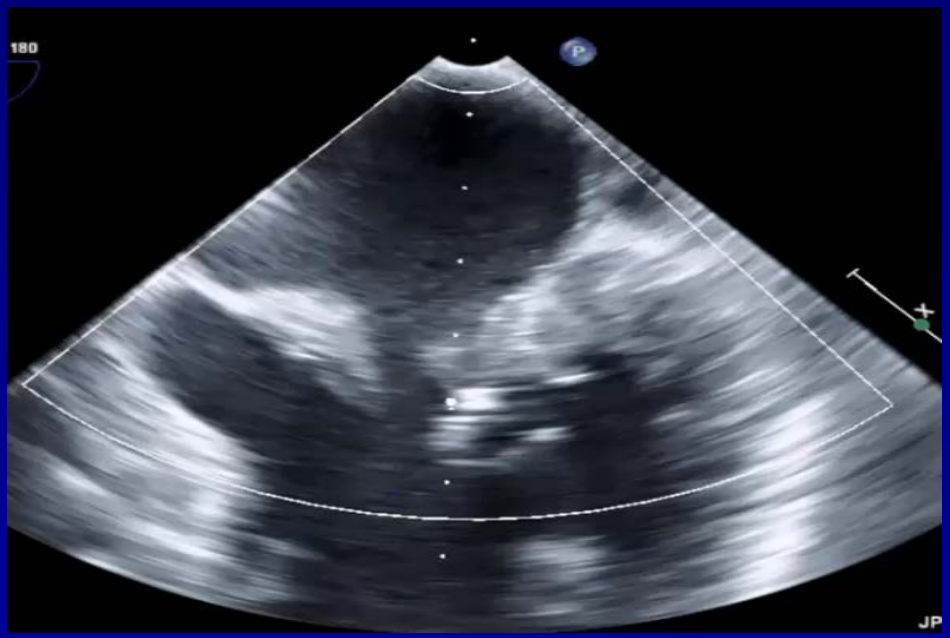
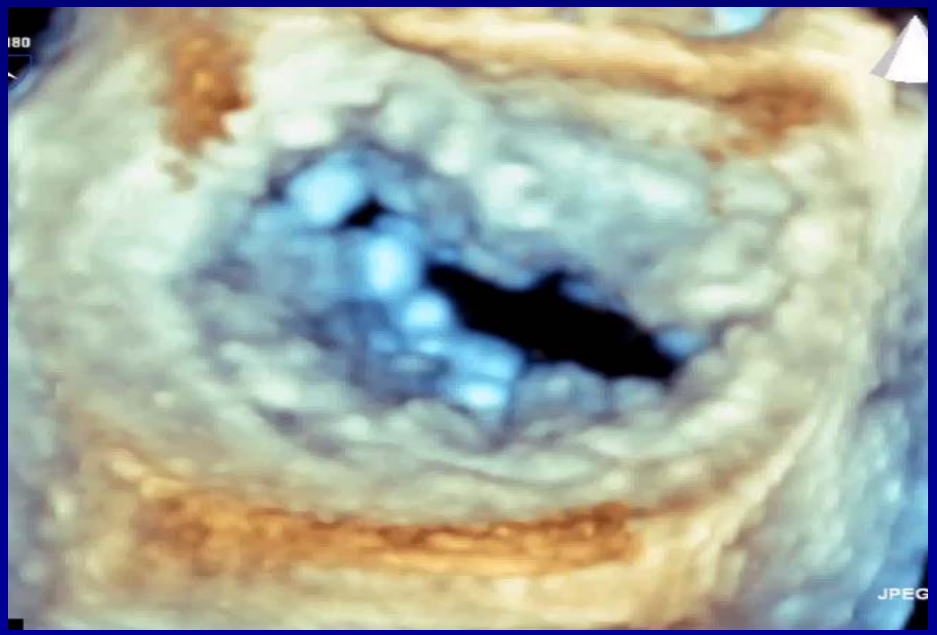
Baseline echo



Five neochords placed





Tact Registry

Outcomes up to 1-Year in the Post-Market Surveillance Registry of the NeoChord Artificial Chordae Delivery System, Model DS1000™

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

Performance Endpoints
MR at Follow-Up Window

	Follow-Up Window									
MR Grade	Baseline		Discharge		30-Days		6-months		1-Year	
0	0	0.0%	25	37.3%	18	28.6%	24	40.7%	18	37.5%
1+	0	0.0%	24	35.8%	27	42.9%	22	37.3%	13	27.1%
2+	3	4.4%	8	11.9%	11	17.5%	3	8.5%	8	16.7%
3+	10	14.7%	8	11.9%	4	6.3%	5	8.5%	2	4.2%
4+	55	80.9%	2	3.0%	1	1.6%	2	3.4%	4	8.3%
Re-Op	0	0.0%	0	0.0%	2	3.2%	3	5.1%	3	6.3%
Eligible Subjects	**68**		**67**		**63**		**59**		**48**	

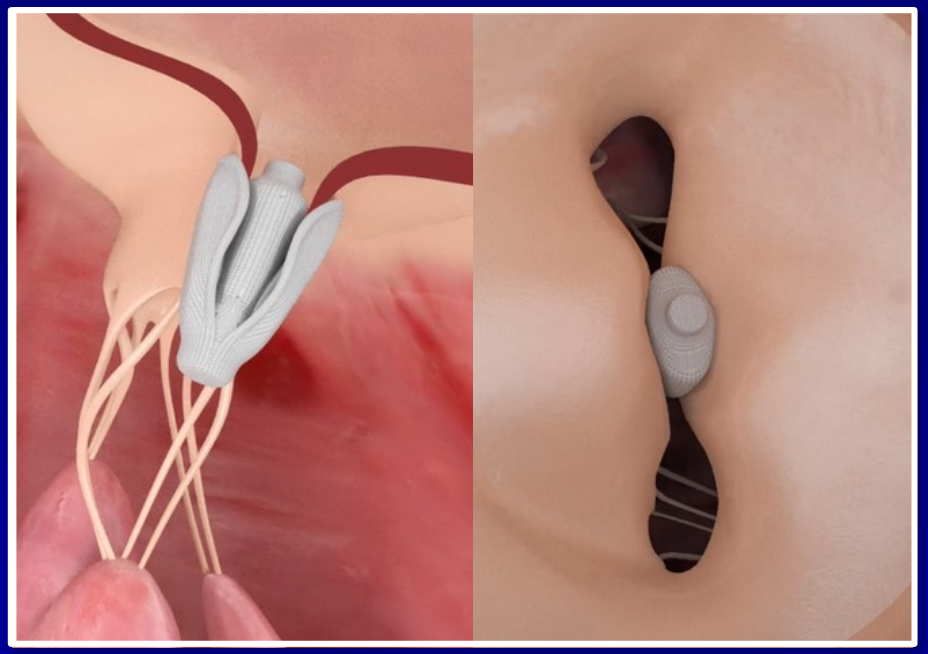
- **At Discharge, 85% of subjects had 0, 1+, 2+ MR**
- **At 30-Days, 89% of subjects had 0, 1+, 2+ MR**
- **At 6-months, 86.5% of subjects had 0, 1+, 2+ MR**
- **At 1-year, 81.3% of subjects had 0, 1+, 2+ MR**

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

Edwards PASCAL Mitral Repair System

Designed to reduce mitral regurgitation

- Transseptal approach
- Spacer is clasped between both mitral valve leaflets
- Independent leaflet clasping
- Simple, intuitive delivery system



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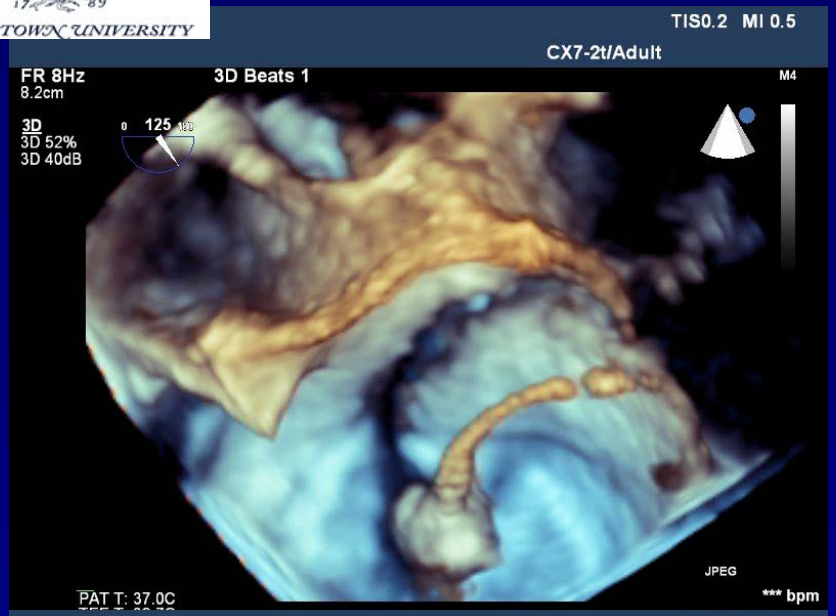
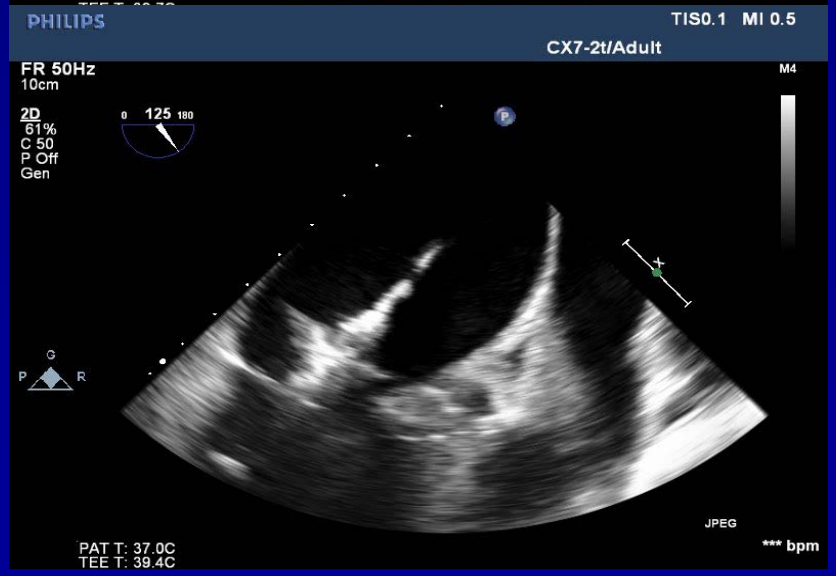
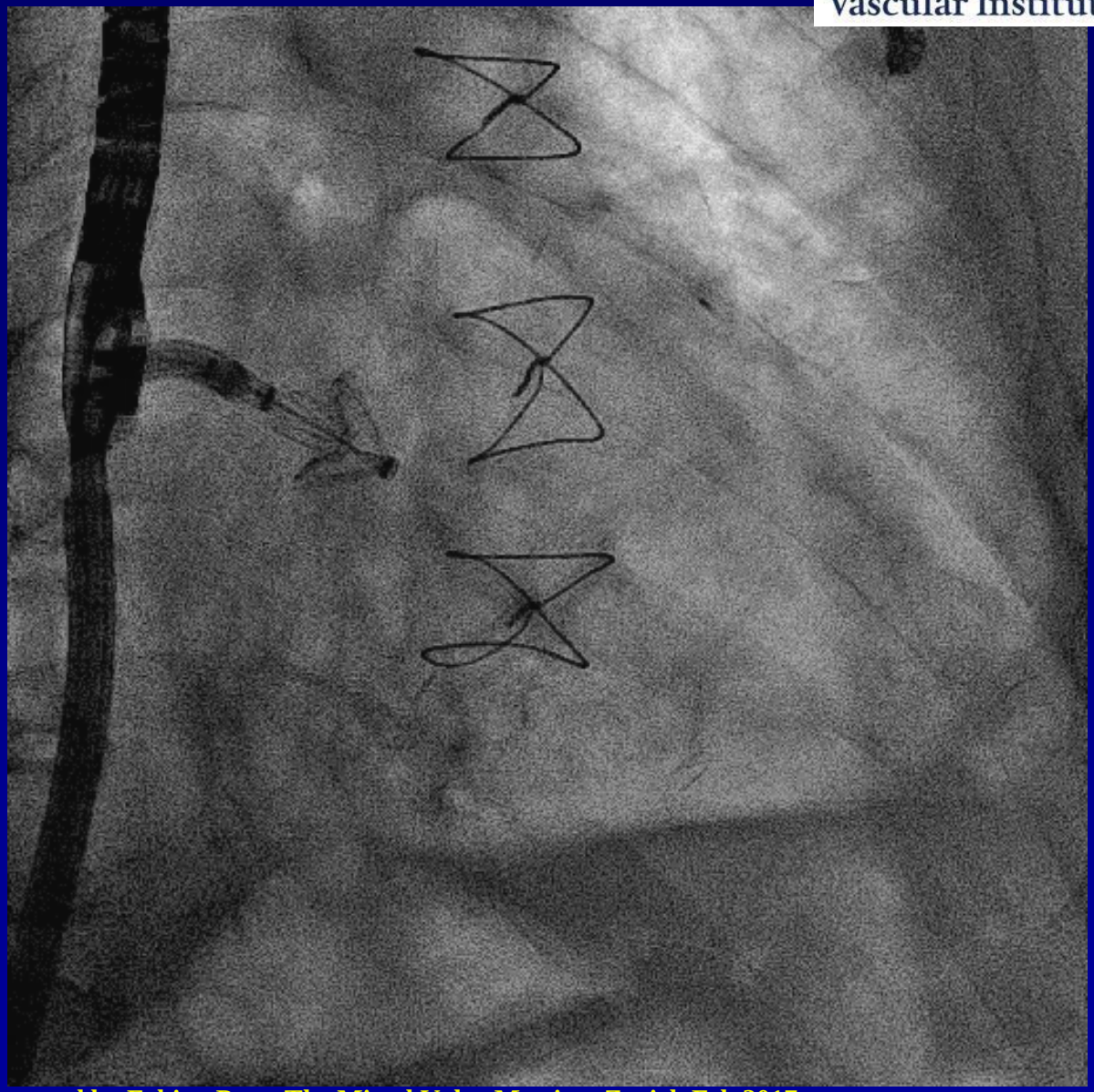
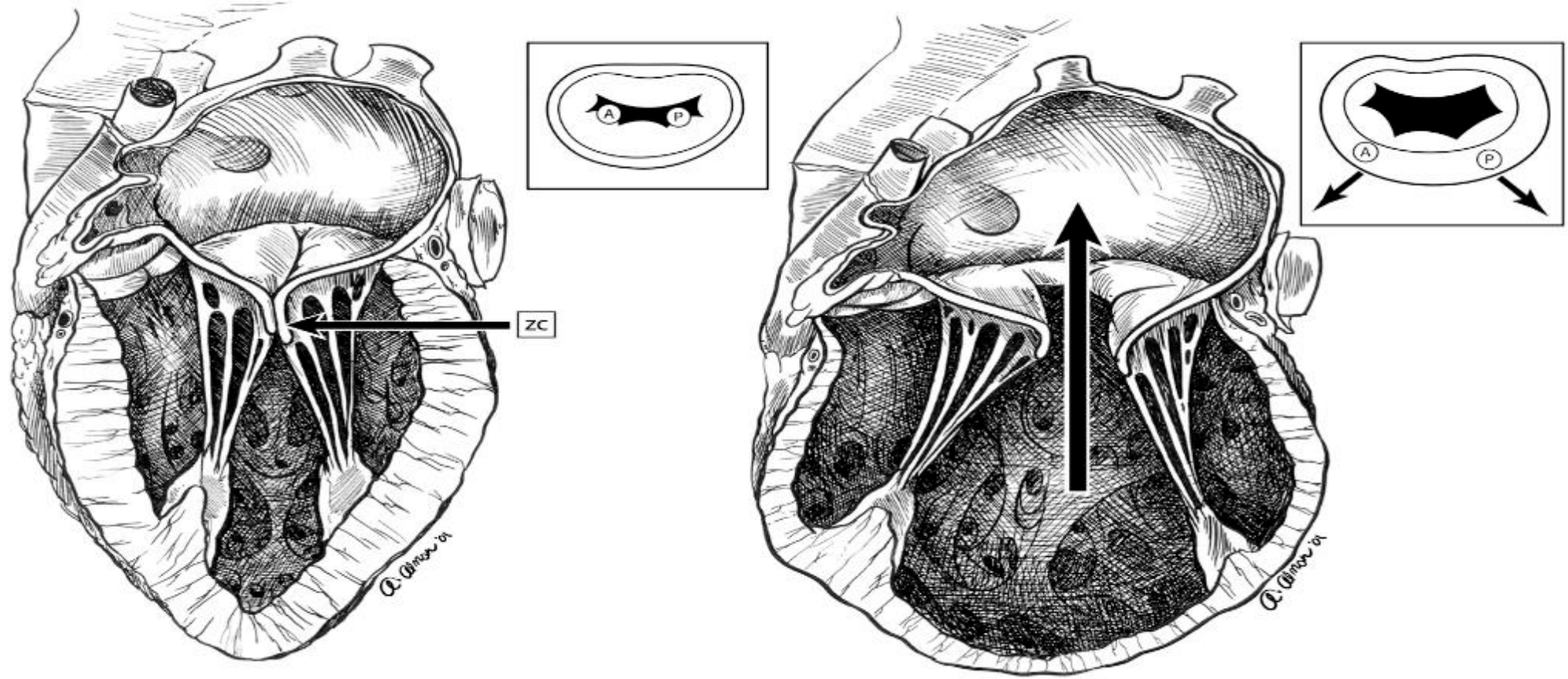






Edwards PASCAL Mitral Repair System presented by Fabian Praz, The Mitral Valve Meeting, Zurich Feb 2017.

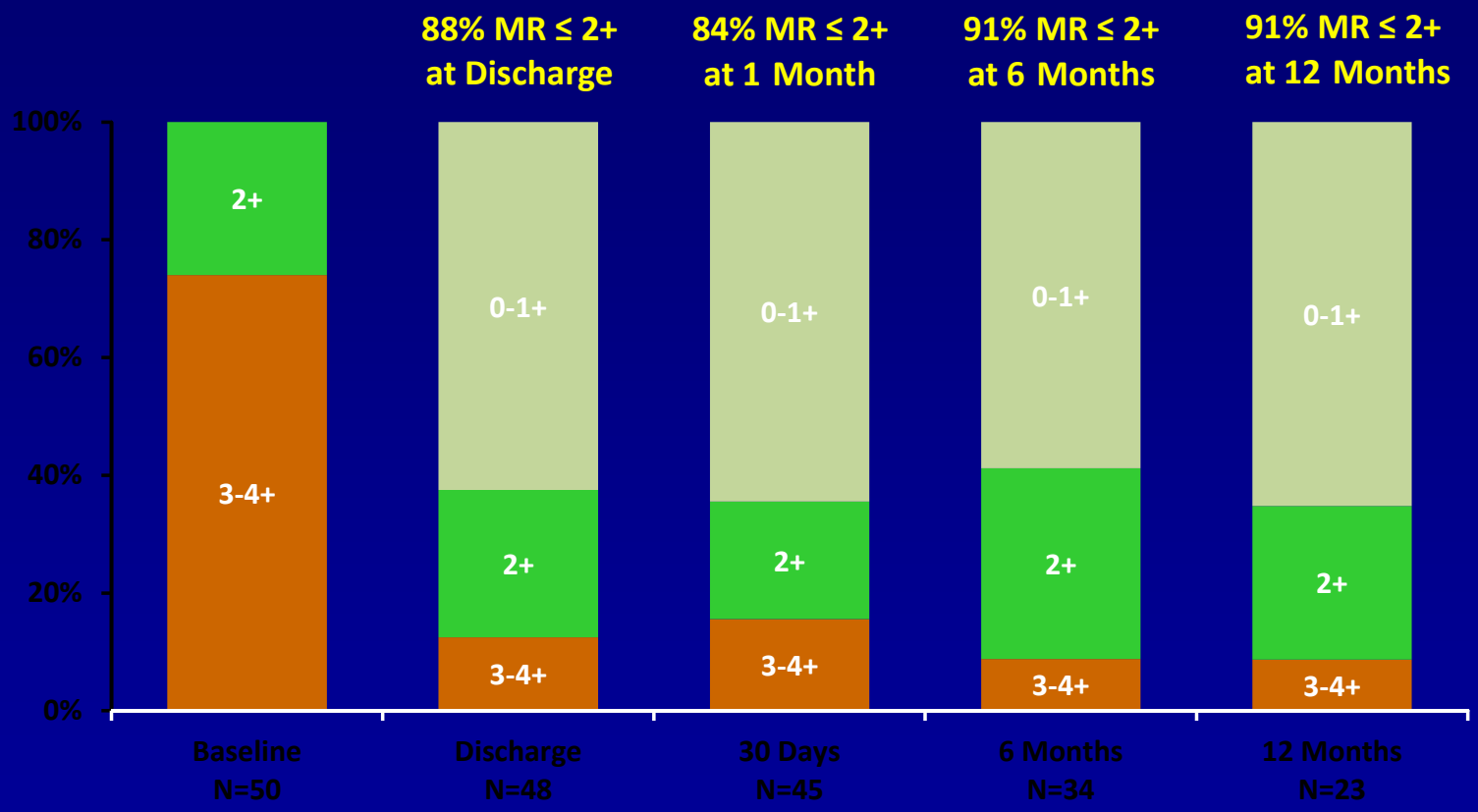
Functional MR : Ventricular Problem!



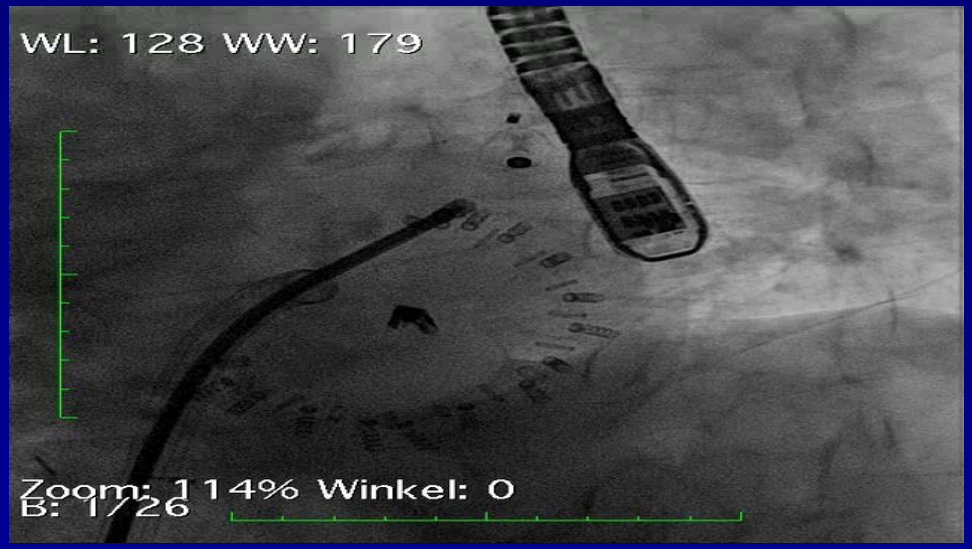
Badhwar, Bolling , chapter in: Advances in Heart Failure, 2004

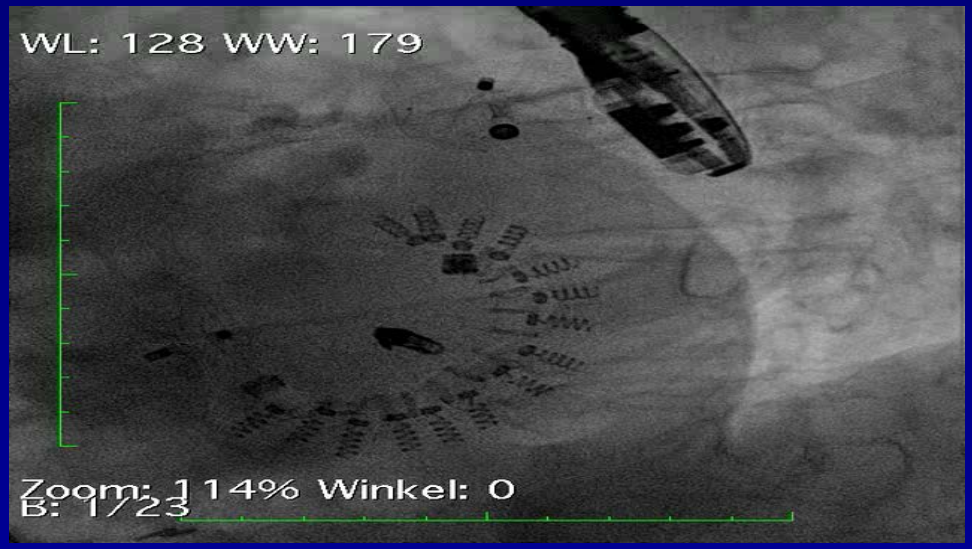
Edwards Cardioband

91% patients with MR≤2+ At 12 Months By Core Lab*



Cardioband + Mitraclip implantation: Pre- and post-adjustment





Courtesy of Valtech

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TMV Replacement
US Early Feasibility Trials

CardiAQ-Edwards

Caisson

Intrepid
(Twelve)

Tendyne

Neovasc Tiara

Transcatheter Mitral Valves in Early Clinical Studies

	Study Type	Region	Status
CardiAQ-Edwards	Early Feasibility	US	Recruiting
	RELIEF (CE Trial)	EU, Canada	Not yet recruiting
Tendyne	Early Feasibility	Global	Recruiting
Twelve	Early Feasibility	Global	Recruiting
Tiara	Early Feasibility	US, Canada, EU	Recruiting
Caisson	Early Feasibility	US	Recruiting

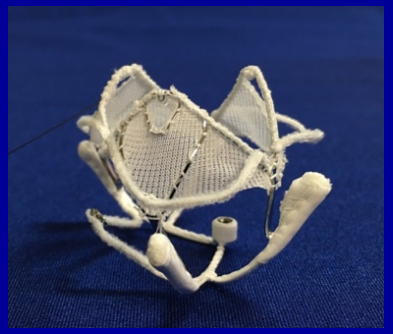
Transcatheter Mitral Valves in Early Clinical Studies

	Both Transseptal and Transapical	Transapical Only			Transseptal Only
	 CardiAQ-Edwards	 Tendyne	 Twelve	 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

Caisson TMVR System

caisson INTERVENTIONAL

=



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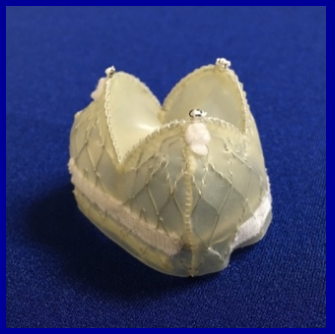
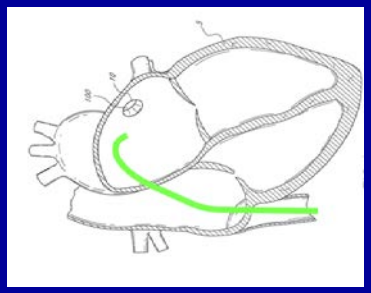
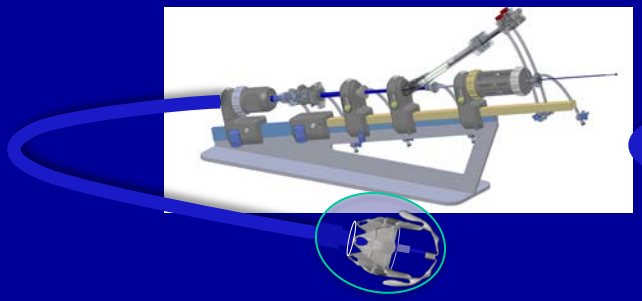
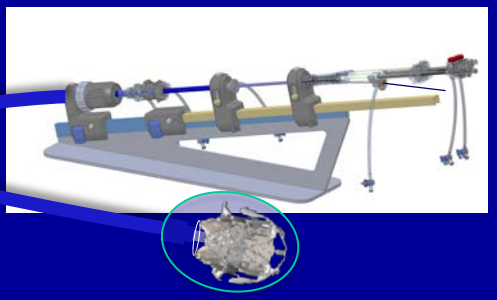








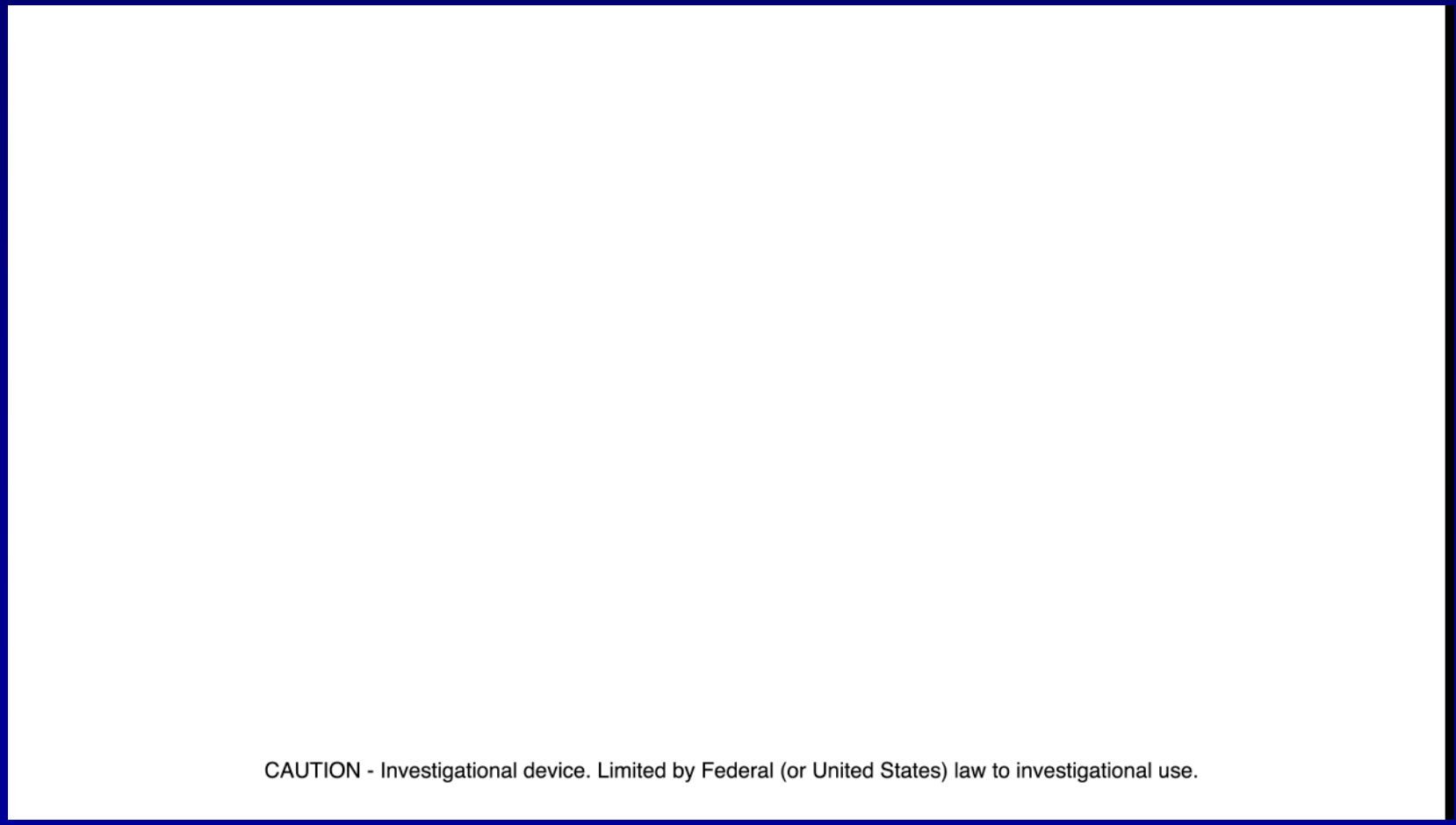
Transeptal System

Controlled Delivery

Repositionable/ Retrievable

Courtesy of Dr. Williams

Procedure Animation



Courtesy of Dr. Williams

FIH Outcomes (n=5)

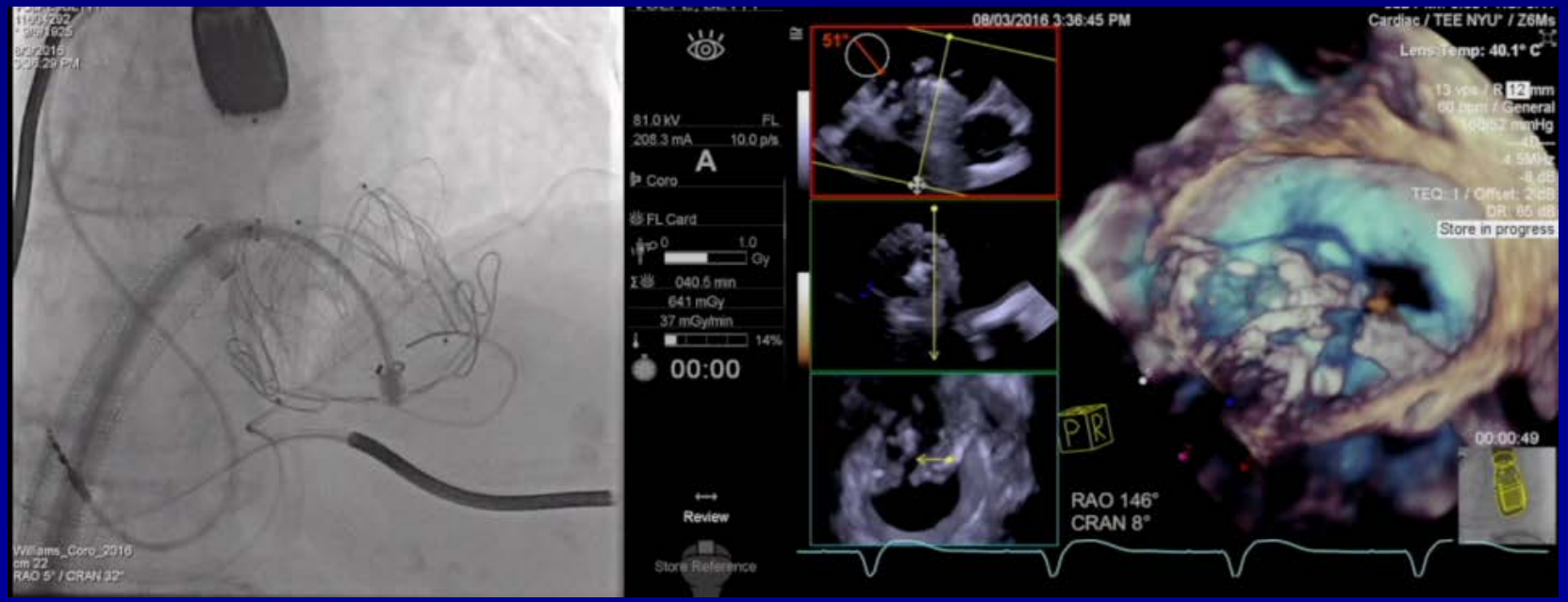
Pt.	Days Since Implant	Status	Intra-Op PVL	30 day PVL	Device Embolization	Device Retrieval
02-001	(28)[1]	Deceased	Mild	None [2]	No	No
02-002	116	Alive	None	None	No	No
SAP	96	Alive	None	None	No	No
02-003	89	Alive	None	Mild	No	No
02-004	N/A[3]	Alive	N/A	N/A	No	Yes

Courtesy of Dr. Williams

1: Death day 28 following Colectomy
2: None on Day 25 TEE
3: Patient received MitraClip following Device Retrieval

Device Retrieval: Pt- 02-004

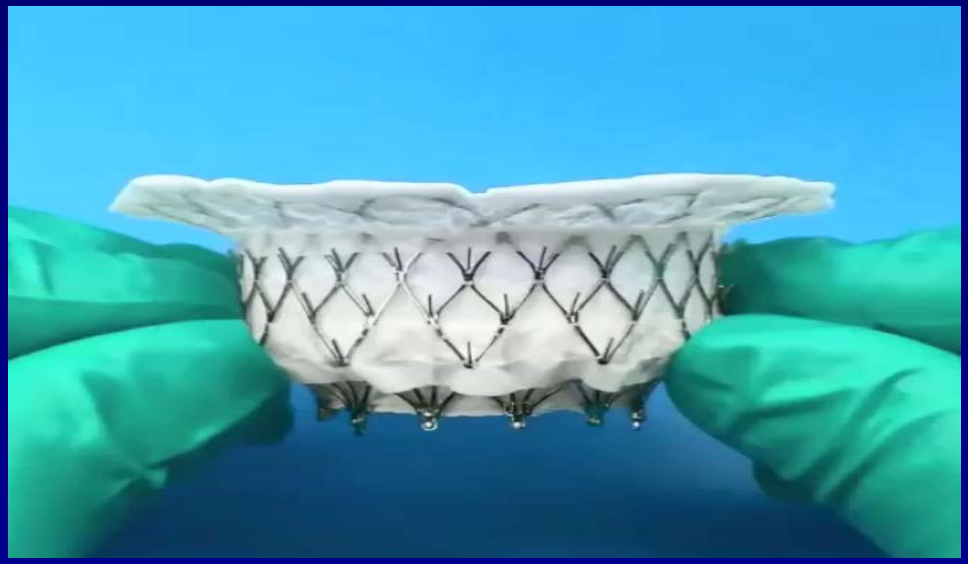
- Leaflet immobility and small orifice area led to inadequate Anchor stability
- Device fully retrieved. Patient received MitraClip treatment in same clinical setting.



Courtesy of Dr. Williams

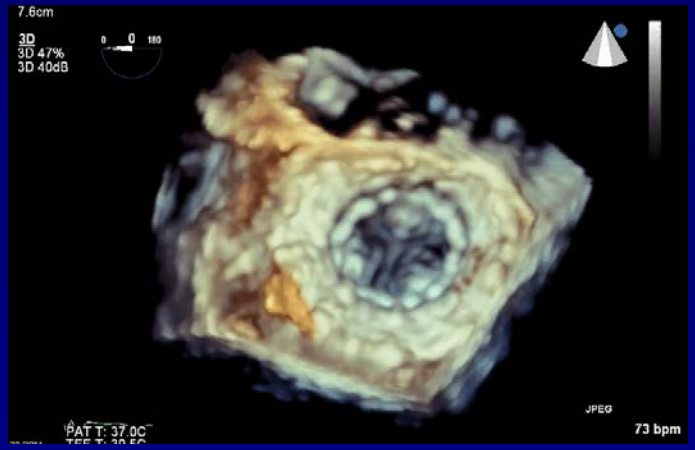
MEDTRONIC INTREPID™ TMVR

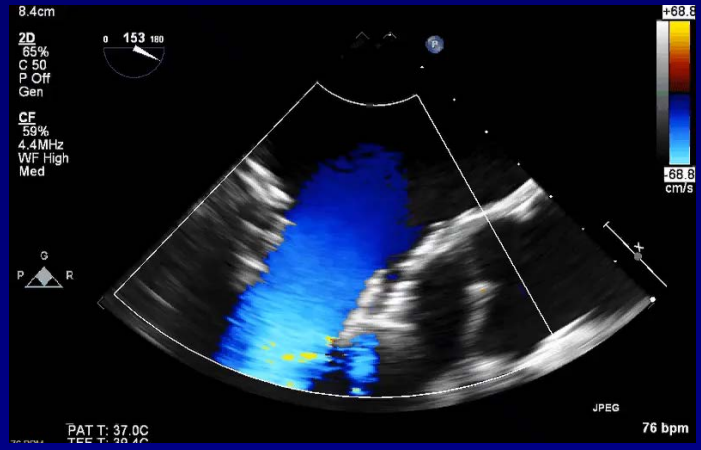
DUAL STENT DESIGN

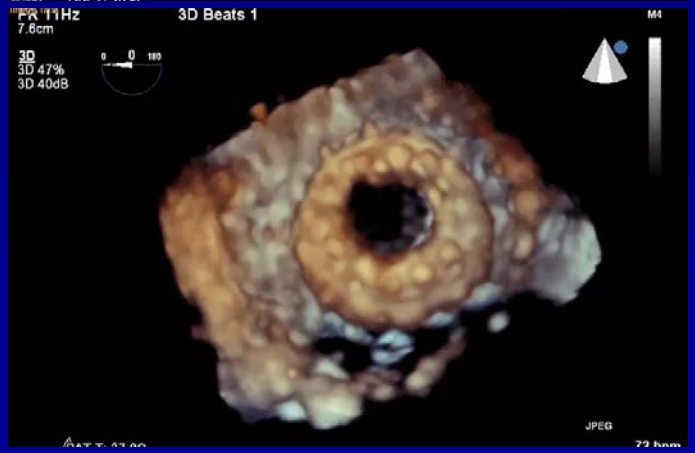


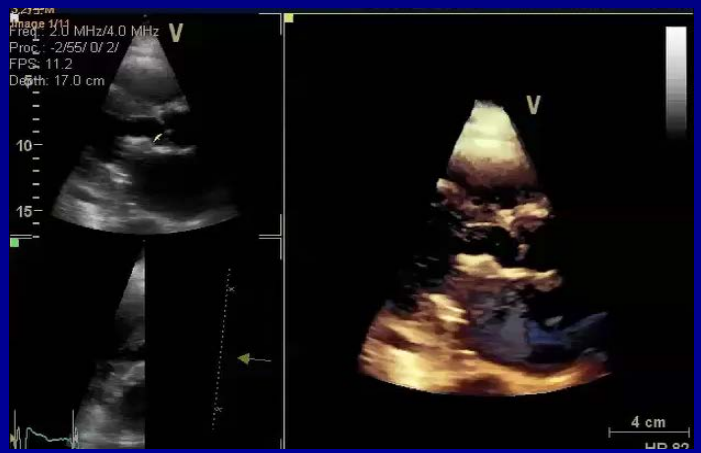
- Conformable Outer Stent engages the annulus and leaflets providing fixation & sealing while isolating the inner stent from the dynamic anatomy
- Circular Inner Stent houses a 27 mm tricuspid bovine pericardium valve
- Flexible Brim aids imaging during delivery & subsequent healing

Medtronic intrepid™ TMVI









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Results
Pilot Study Clinical experience

Procedural Outcomes (n=39)

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

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

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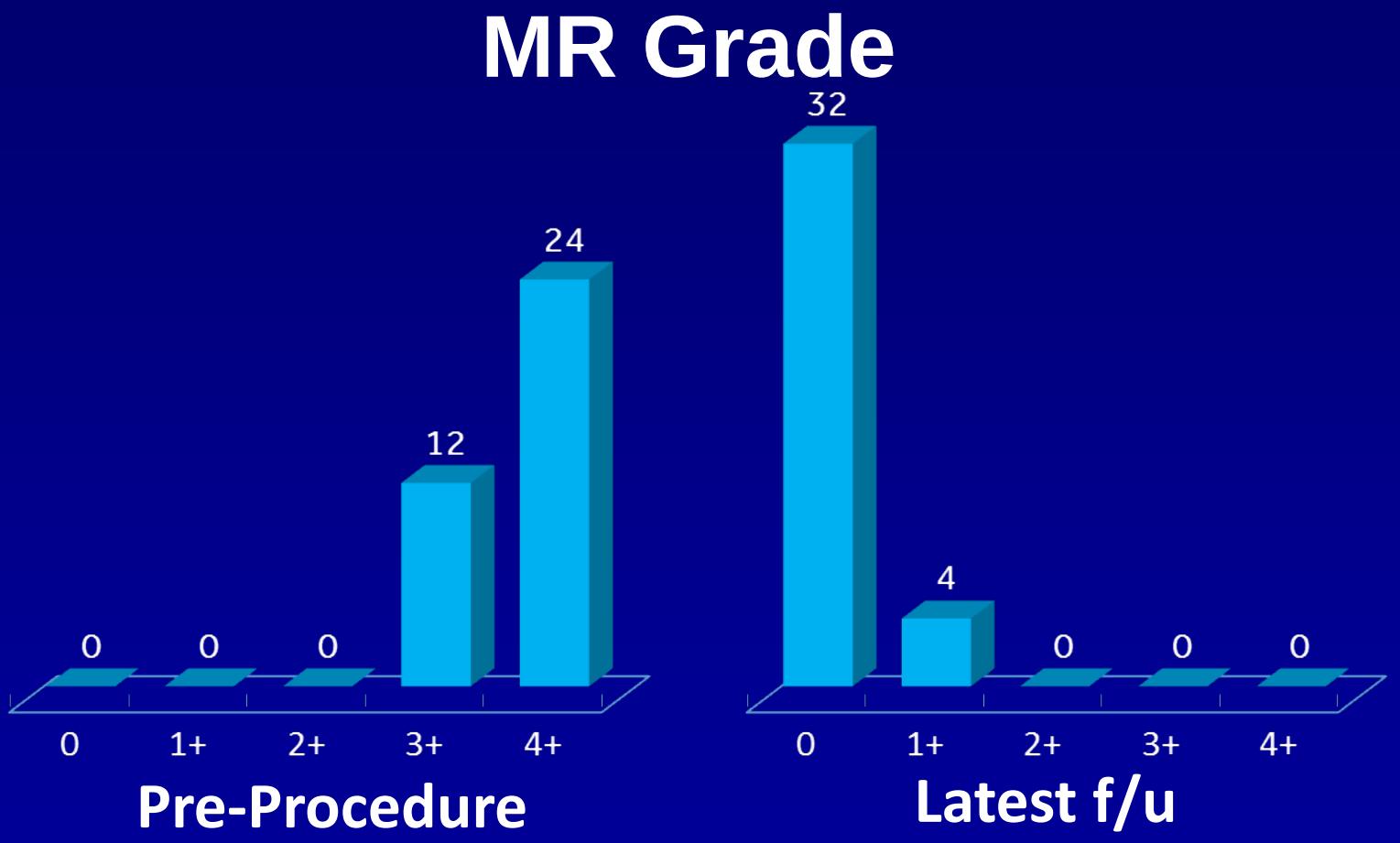
Results

Pilot Study Clinical experience



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Edwards-CardiAQ

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

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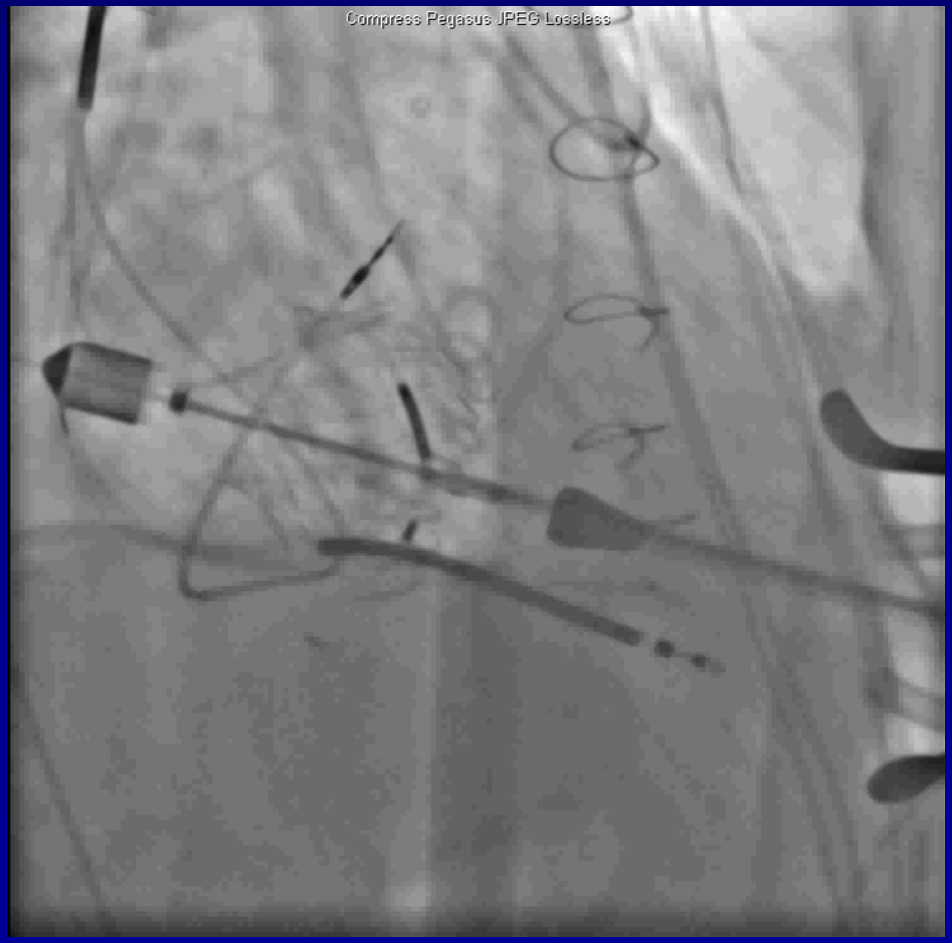
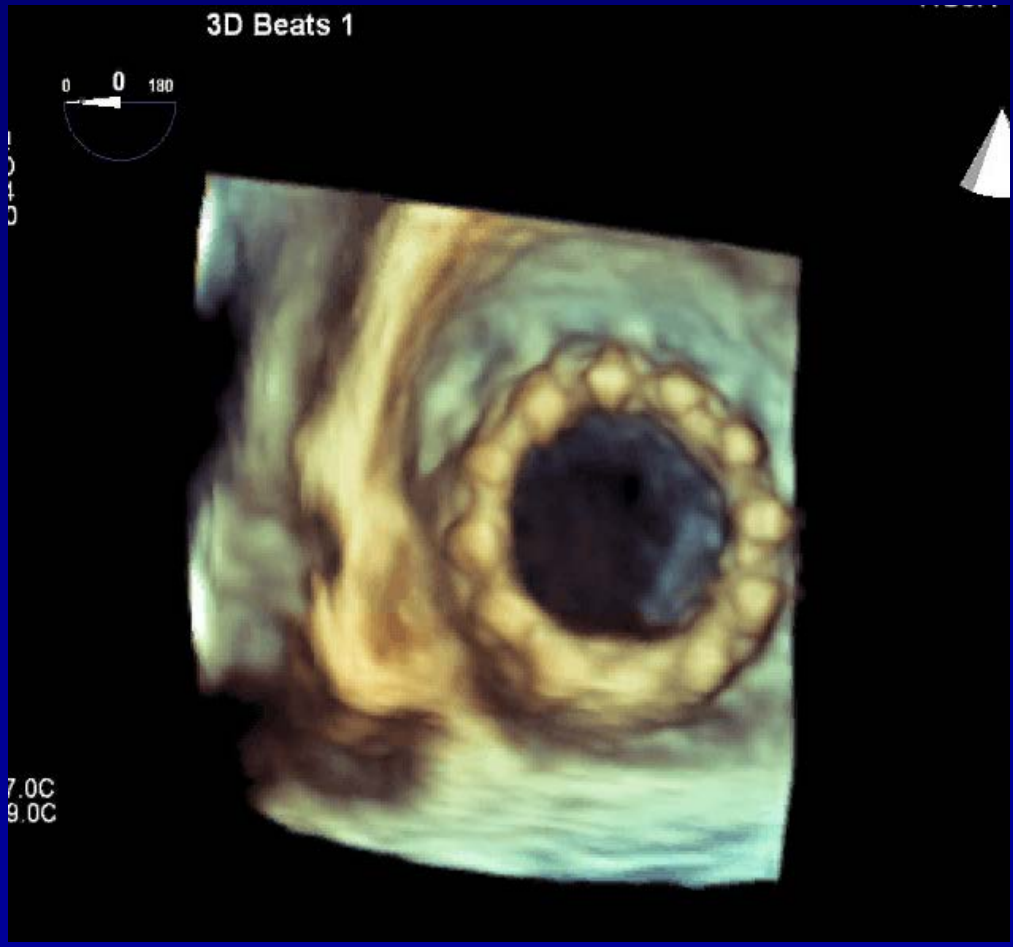
CardiAQ-Edwards TMVR





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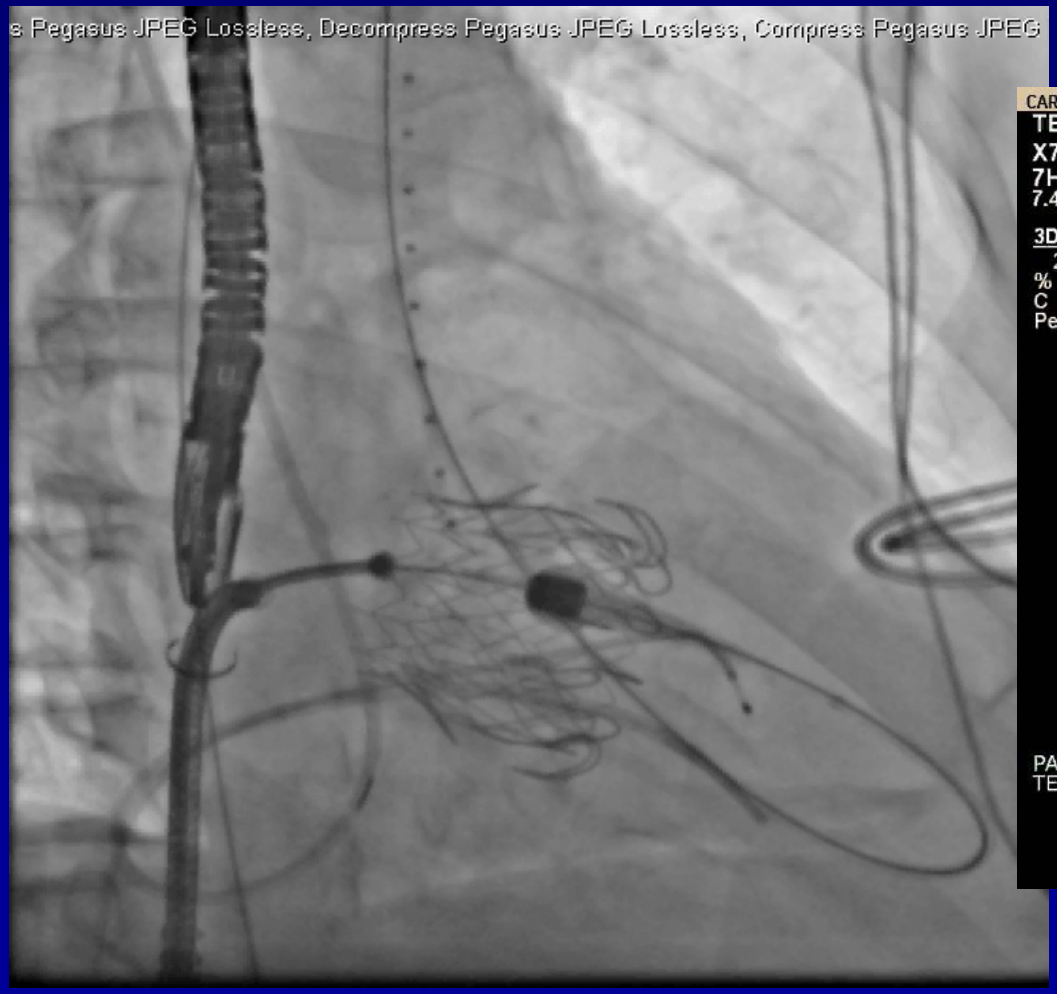
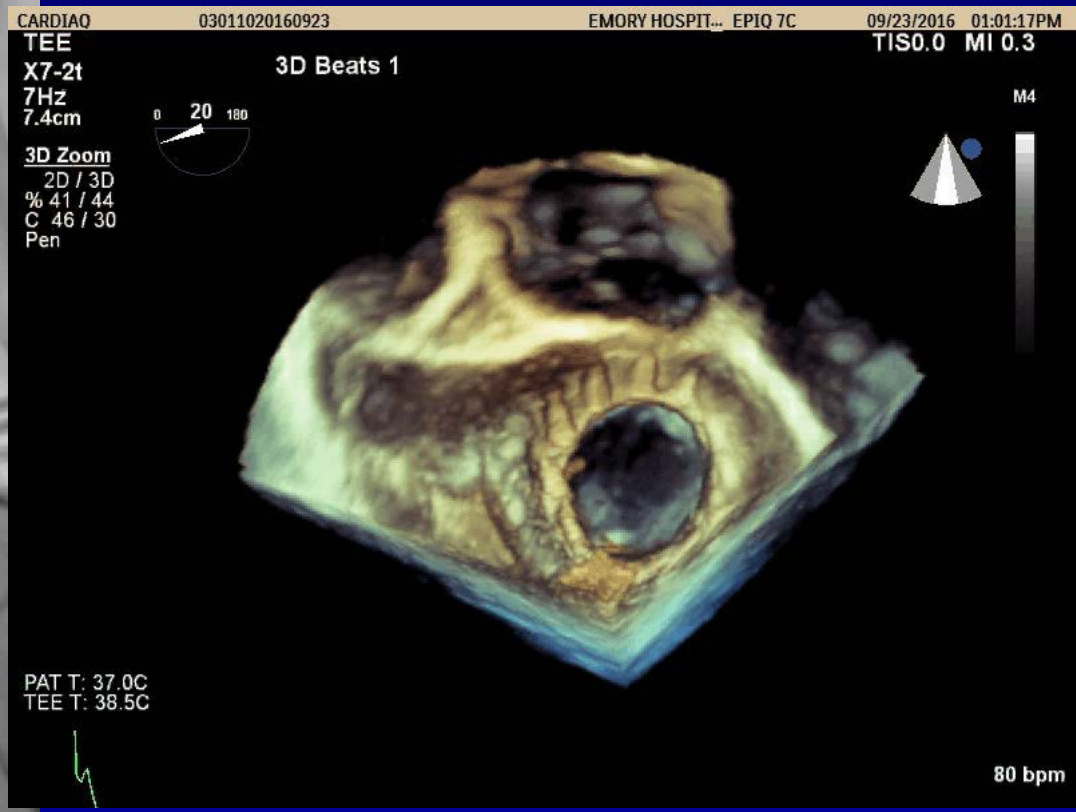
CardiAQ-Edwards TMVR: Transseptal

Valve Release





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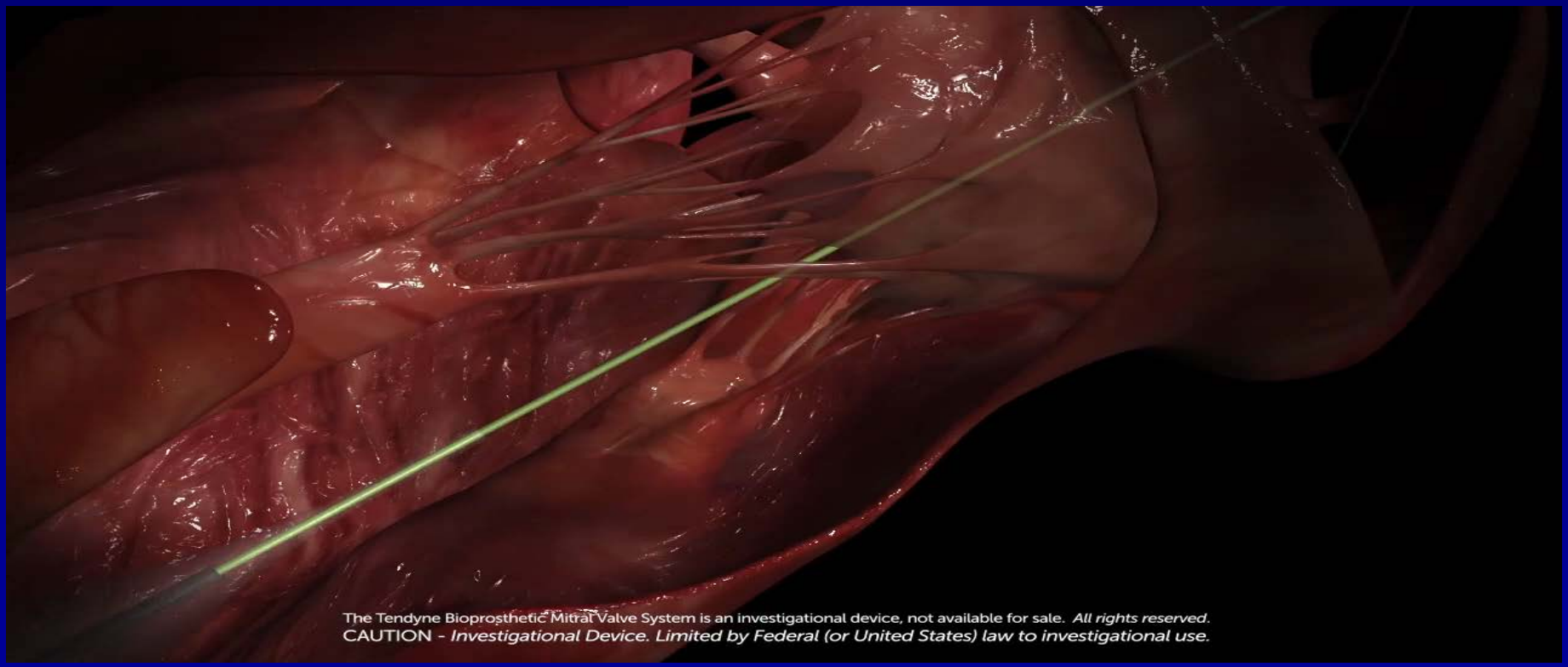
Abbott Tendyne Implant Video



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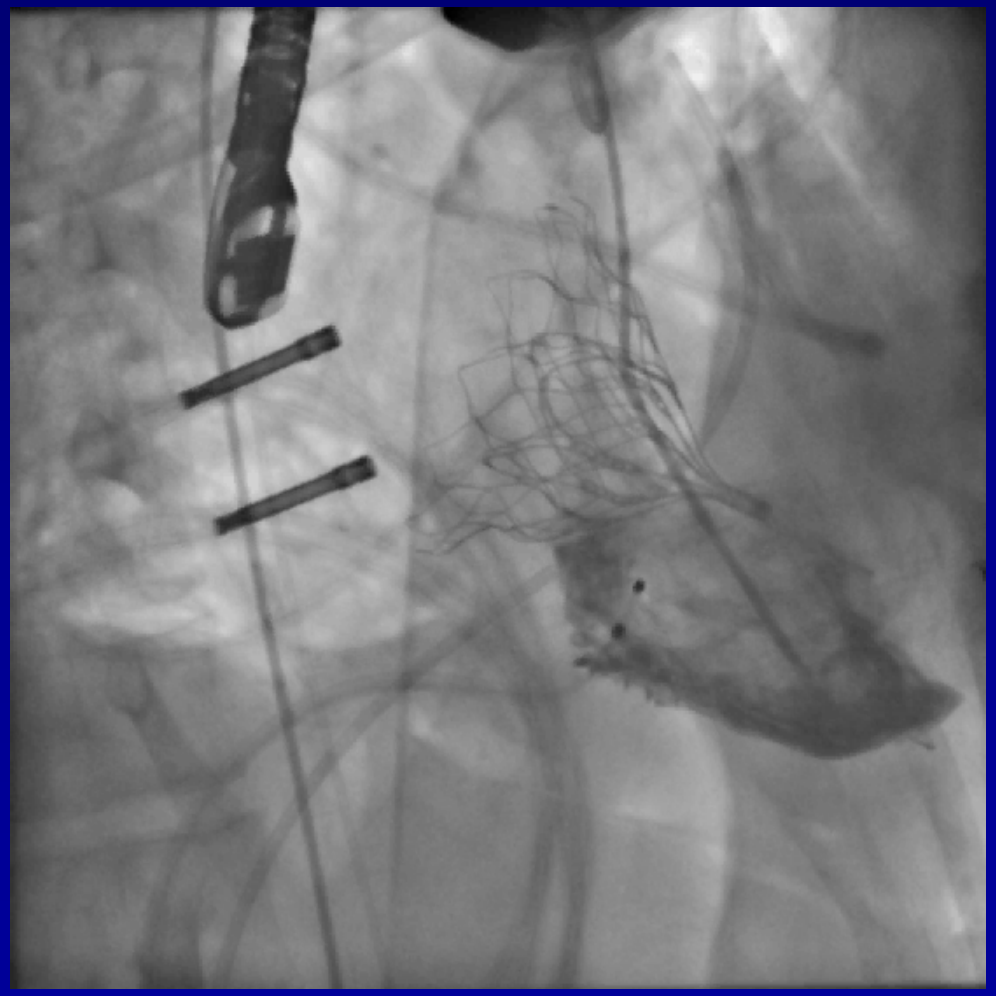
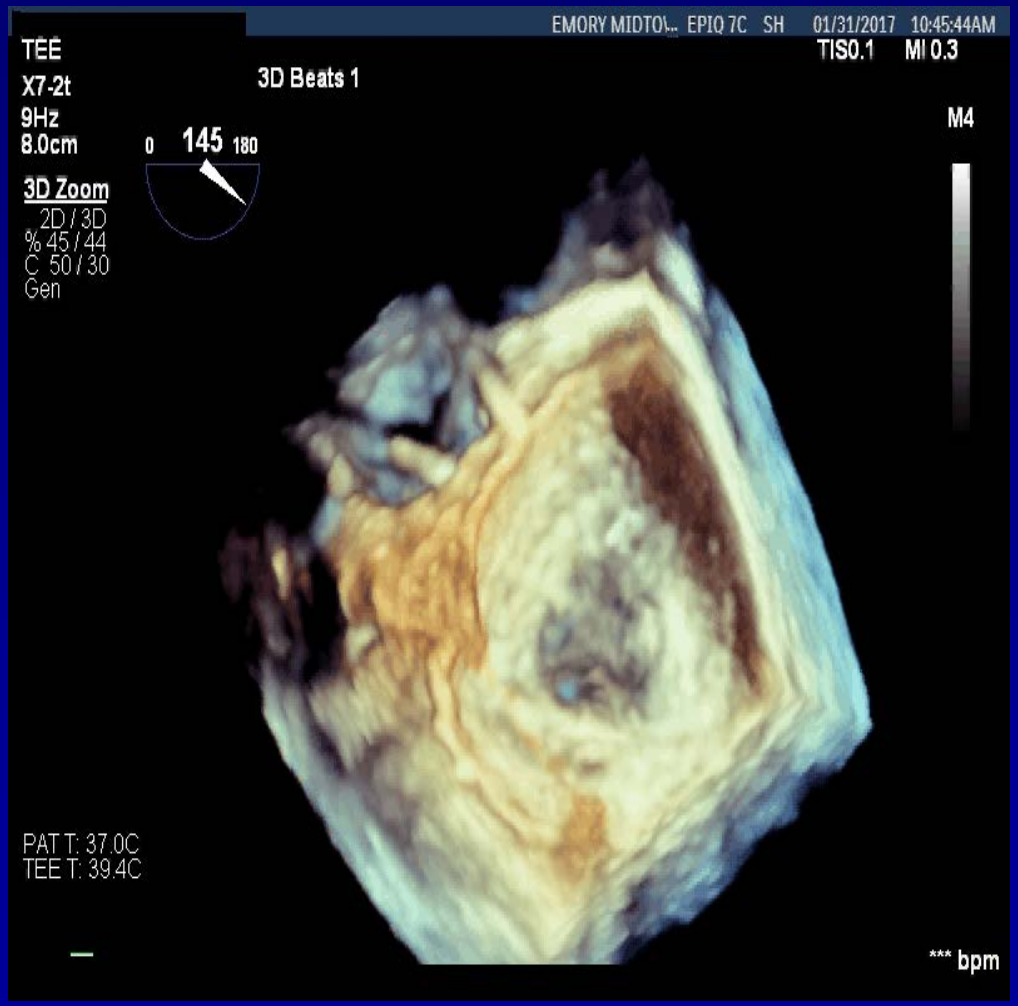
Abbott Tendyne Implant Video





Abbott Tendyne TMVI: D30 Outcomes

Outcome	N=30
Death (all cause)	1 (3.3%)
Cardiac	0 (0%)
Non-cardiac	1 (3.3%)
CVA	0 (0%)
MV surgery	0 (0%)
Re-hospitalisation	
Heart failure	4 (13.8%)
LVAD/transplant	0 (0%)
Other (ileus)	1 (3.3%)
Device-related	
Hemolysis, transfusion	1 (3.3%)
Leaflet thrombosis	1 (3.3%)

D. Muller, TCT 2016

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**

Thank You

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