TMVRepair toolbox: Clip, Chord, Ring or Hybrid?

Hong Kong College of Cardiology 28th Annual Scientific Congress

3 July 2020 (Friday) Heart Team Symposium: A Case-based Approach

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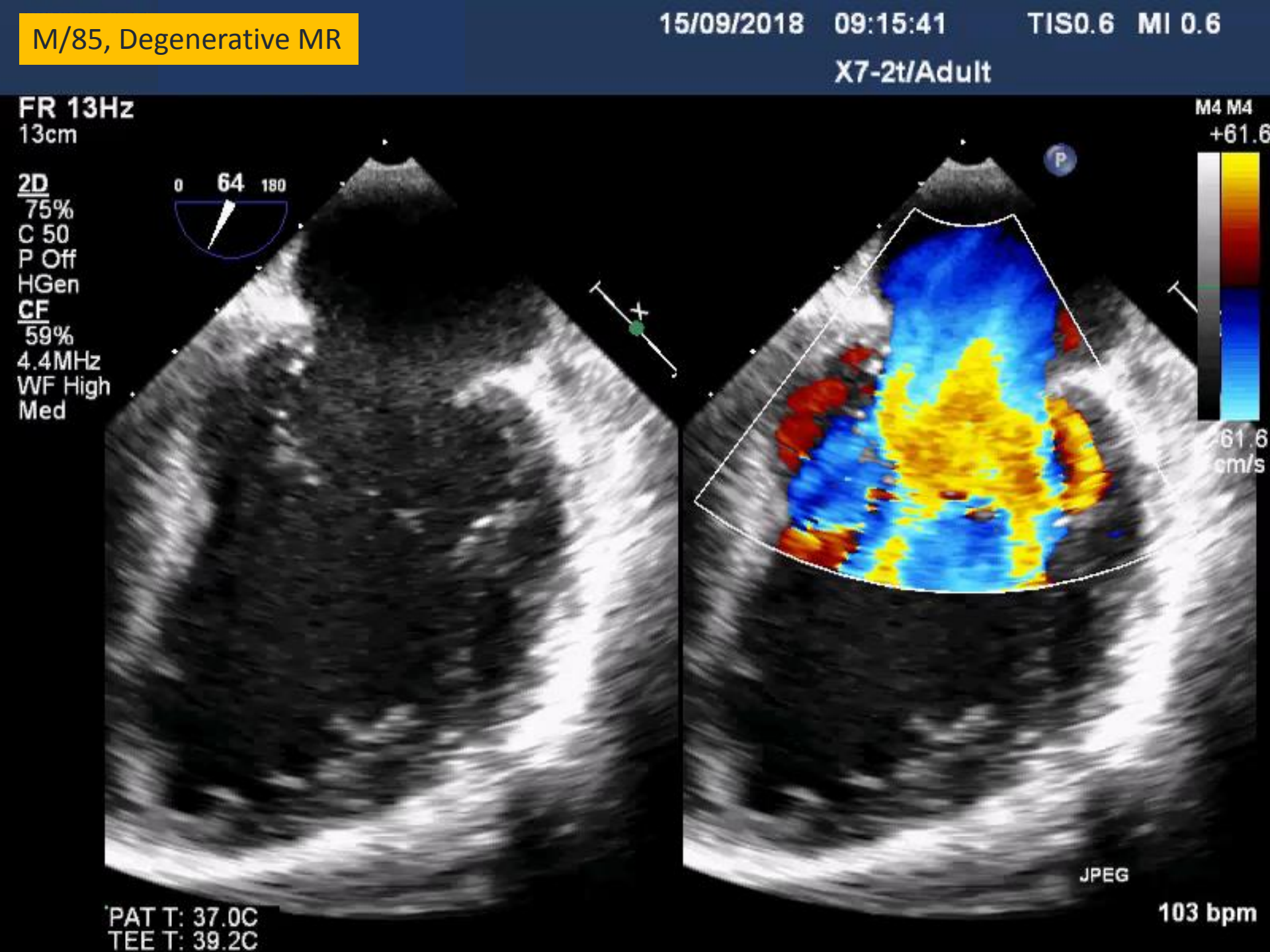
HKU Med


What is inside the TMV Repair toolbox?

MitraClip [Abbott Structural]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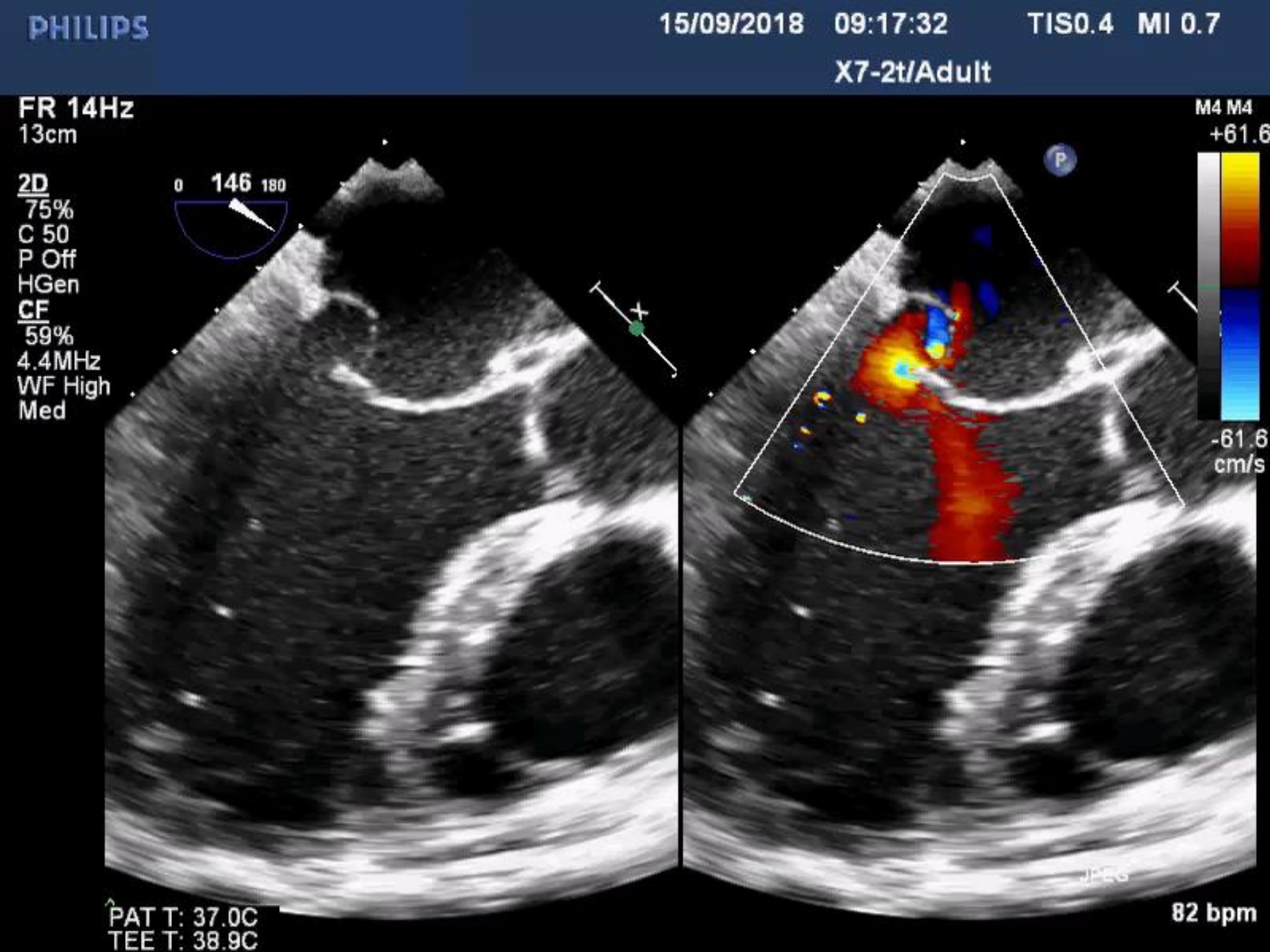
13cm
2D
75%
C 50
P Off
HGen
CF
59%
4.4MHz
WF High
Med
0 64 180
M4 M4
+61.6
61.6
cm/s
JPEG
PAT T: 37.0C
TEE T: 39.2C
103 bpm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C 50
P Off
HGen
CF
59%
4.4MHz
WF High
Med
0 146 180
M4 M4
+61.6
-61.6
cm/s
PAT T: 37.0C
TEE T: 38.9C
82 bpm


PHILIPS
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X7-2t/Adult
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3D Beats 1
M4
3D
3D 47%
3D 40dB
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JPEG
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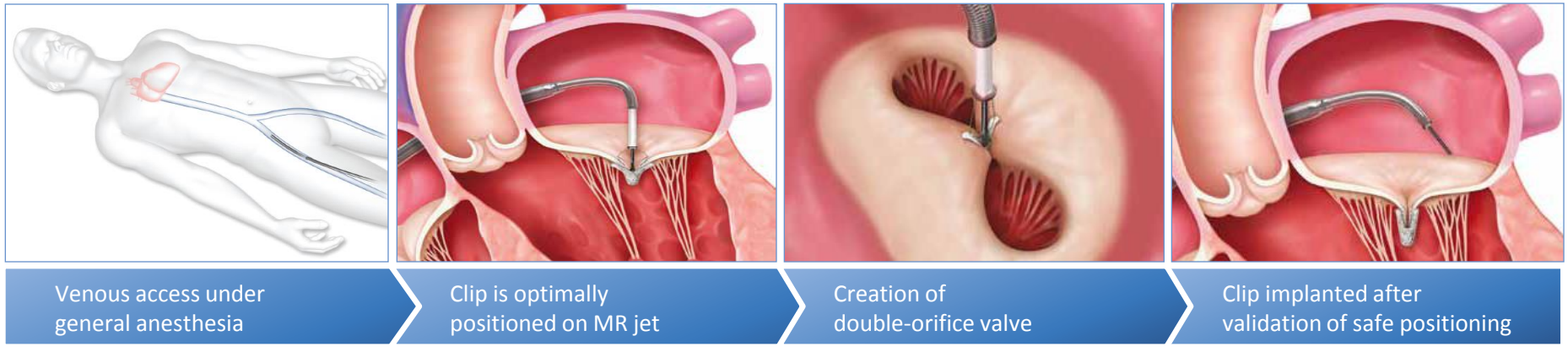
TEE T: 38.0C
80 bpm

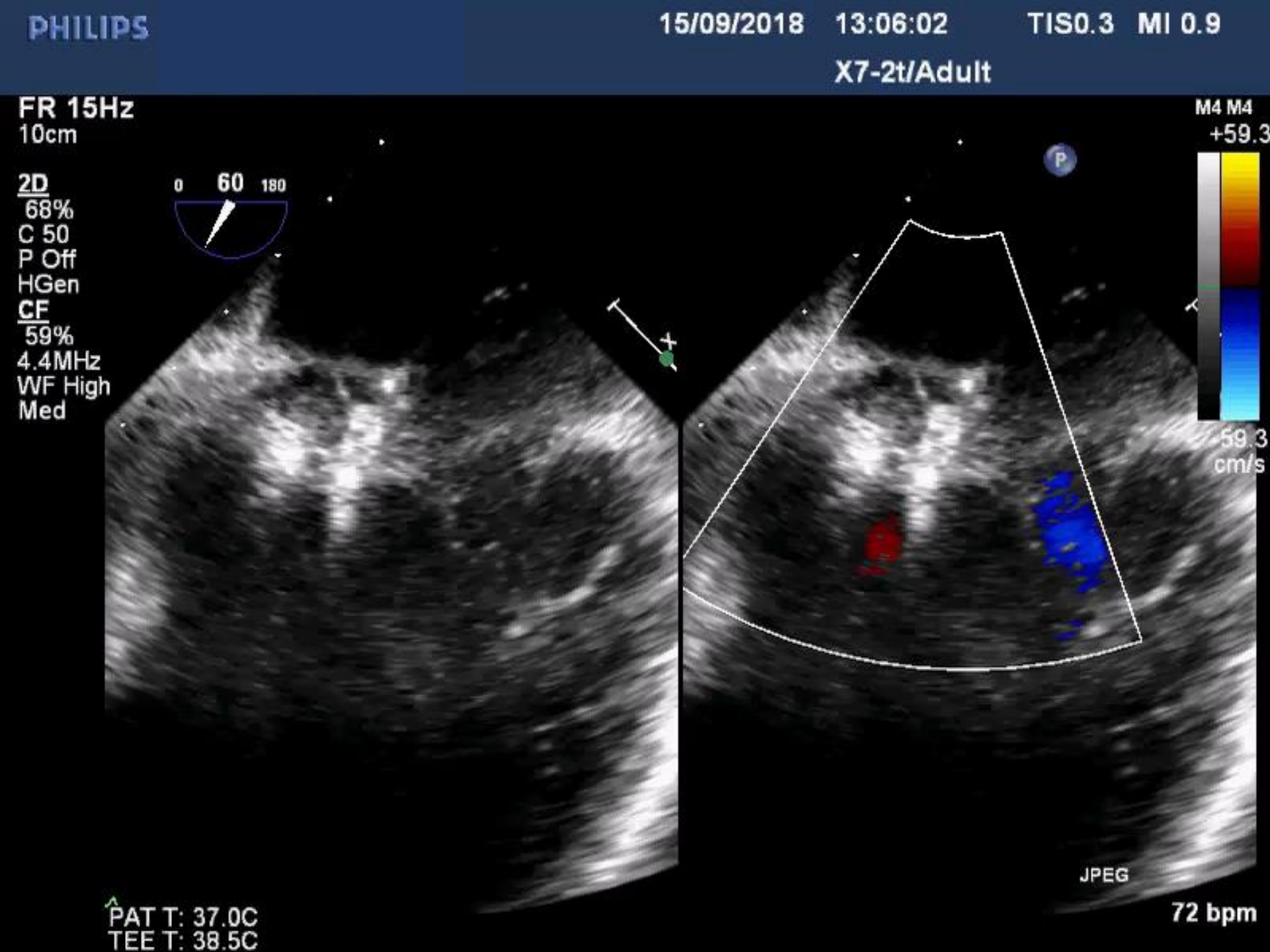
Key Principles of the MitraClip Procedure



- Mitral repair without arresting the heart (no need for cardiopulmonary bypass)
- Mitral regurgitation assessed in real time within beating heart allowing repositioning of the clip until desired outcome is obtained
- Systematic and safe procedure
- Surgical intervention remains preserved


PHILIPS
15/09/2018 11:08:20 TIS0.4 MI 0.7
MH
X7-2t/Adult
FR 4Hz
7.0cm
3D Beats 1
M4
3D
3D 47%
3D 40dB
0 65 180
PAT T: 37.0C
TEE T: 39.0C
55bpm


Im: 1/3
Se: 68
1/6/1949 M
Queen Mary Hospital
1204-2018
XA
Left Coronary 15 fps
WL: 129 WW: 190 [D]
AP
15/9/2018 12:55:35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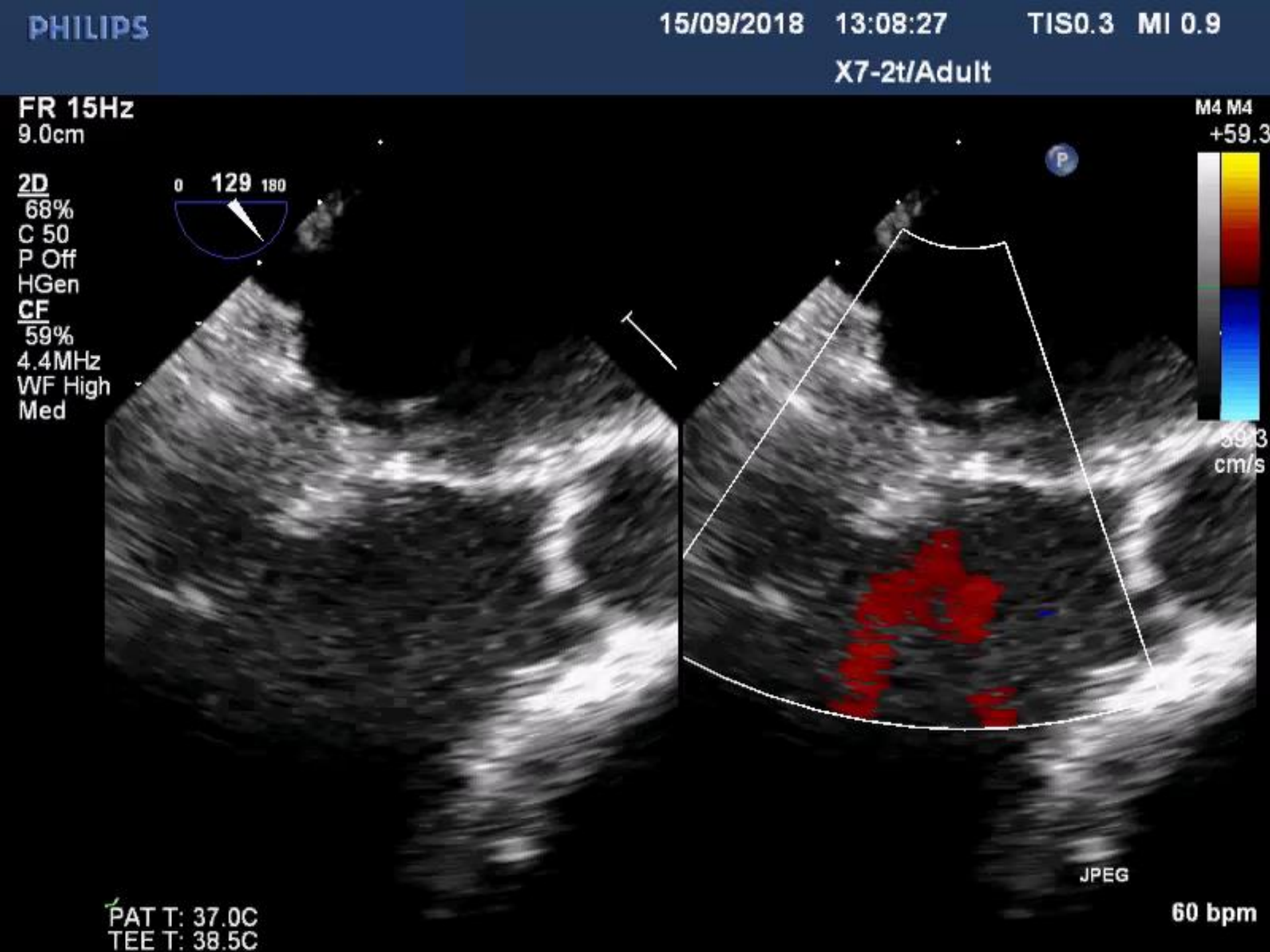
FR 15Hz
10cm
2D
68%
C 50
P Off
HGen
CF
59%
4.4MHz
WF High
Med
0 60 180
M4 M4
+59.3
-59.3
cm/s
JPEG
72 bpm
PAT T: 37.0C
TEE T: 38.5C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68%
C 50
P Off
HGen
CF
59%
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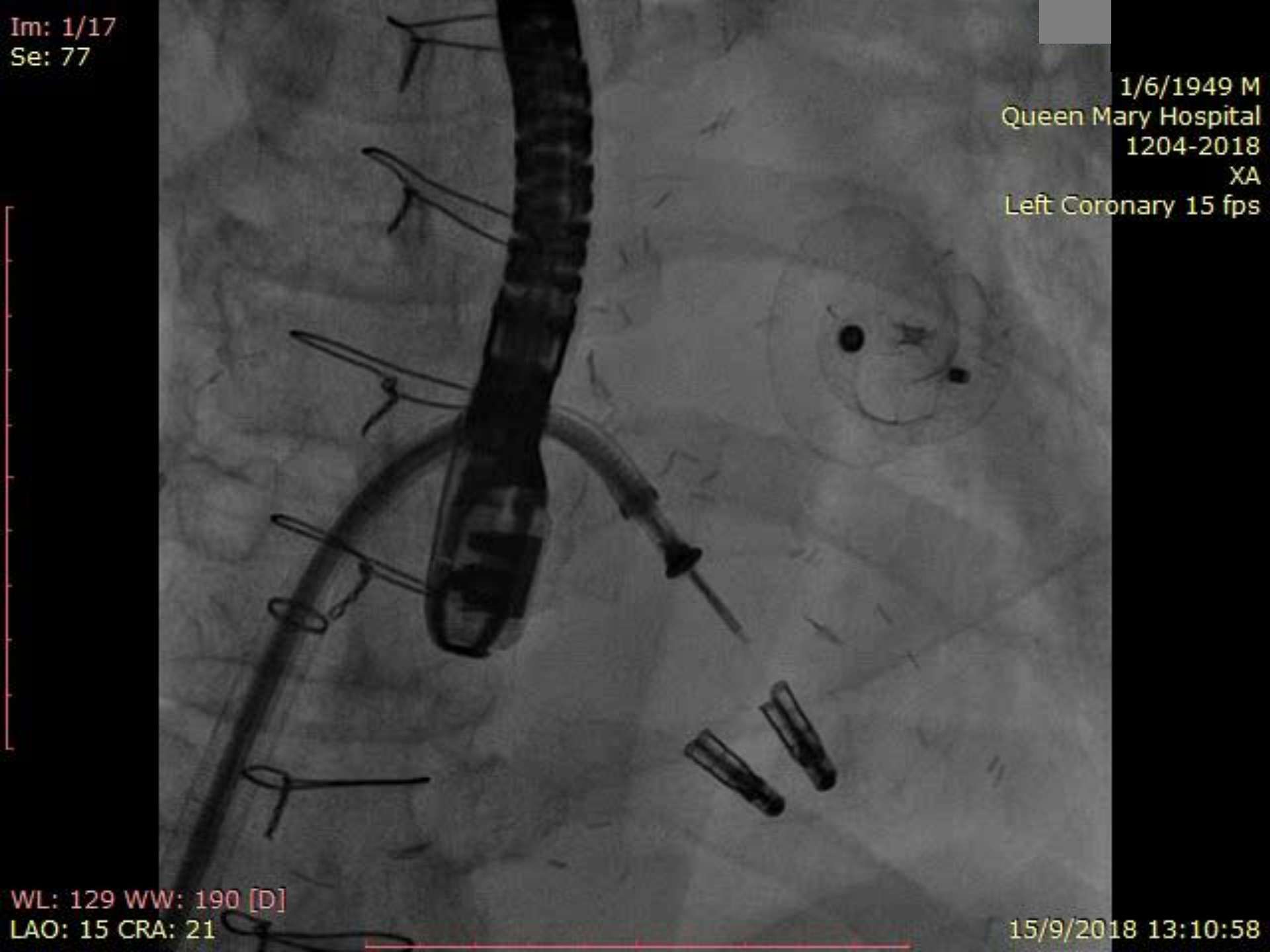
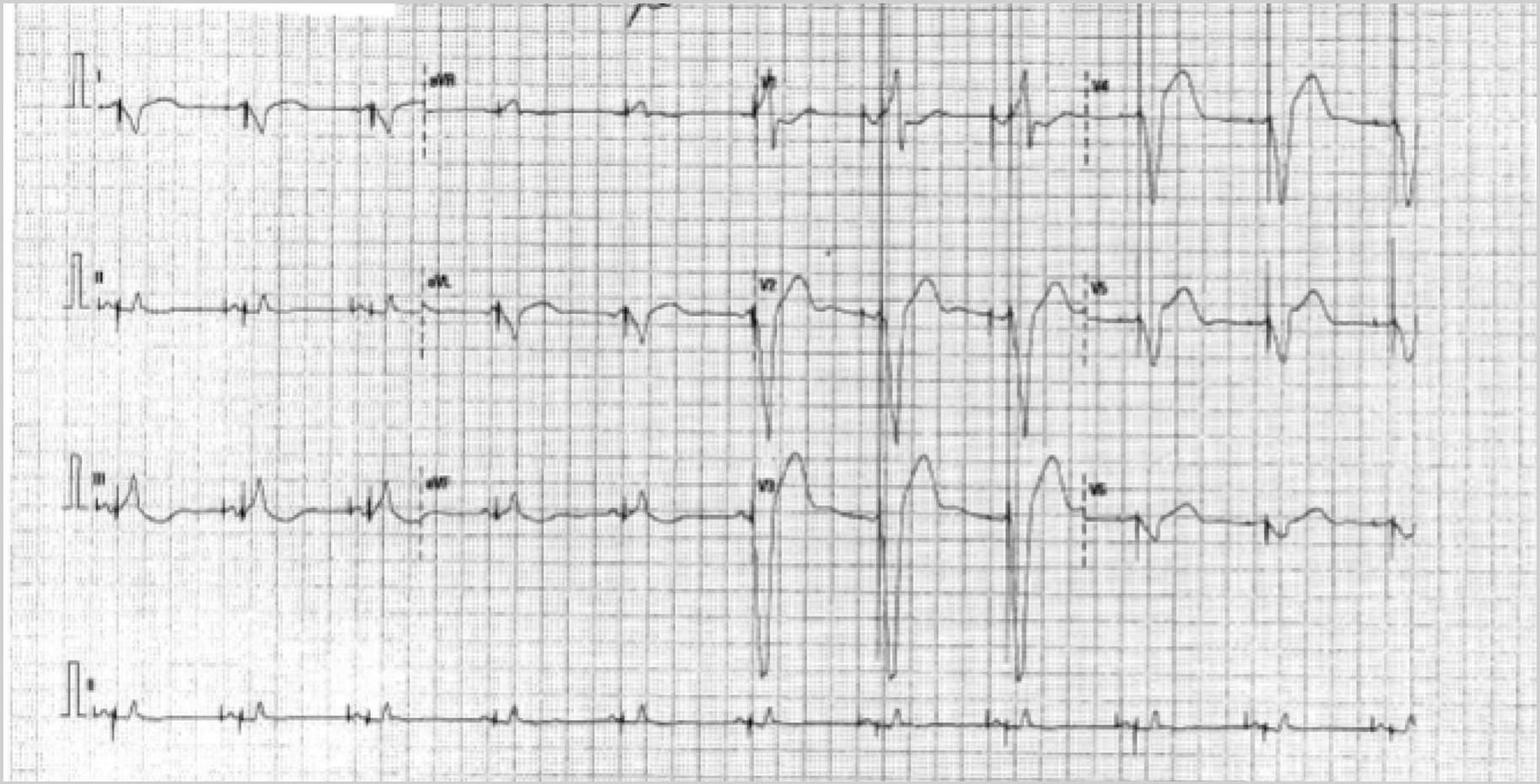
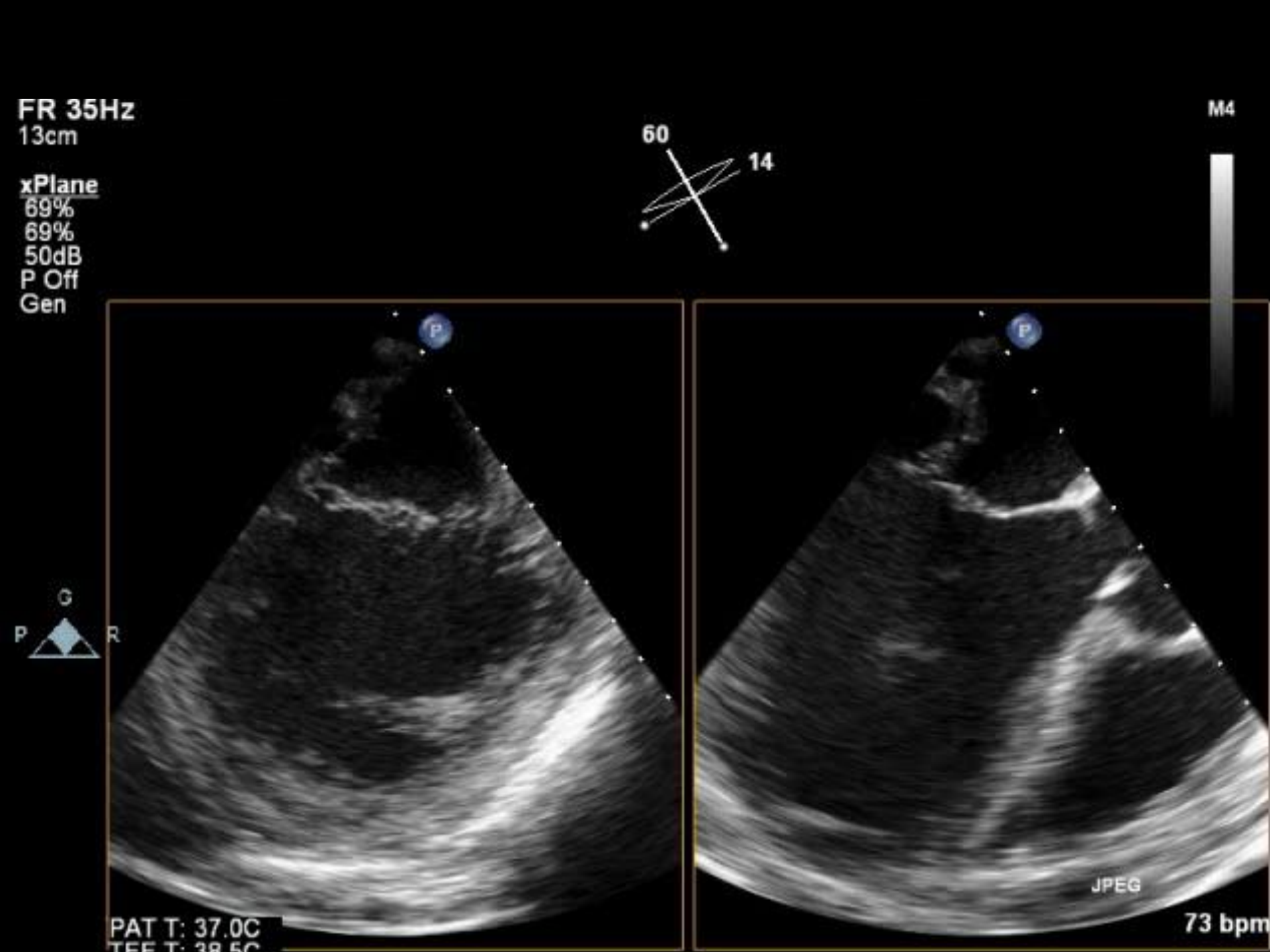
WF High
Med
0 129 180
M4 M4
+59.3
cm/s
JPEG
60 bpm
PAT T: 37.0C
TEE T: 38.5C


Im: 1/17
Se: 77
1/6/1949 M
Queen Mary Hospital
1204-2018
XA
Left Coronary 15 fps
WL: 129 WW: 190 [D]
LAO: 15 CRA: 21
15/9/2018 13:10:58

M/70, DCMP Functional MR, LVEF 20%, CRT-D




FR 35Hz
13cm
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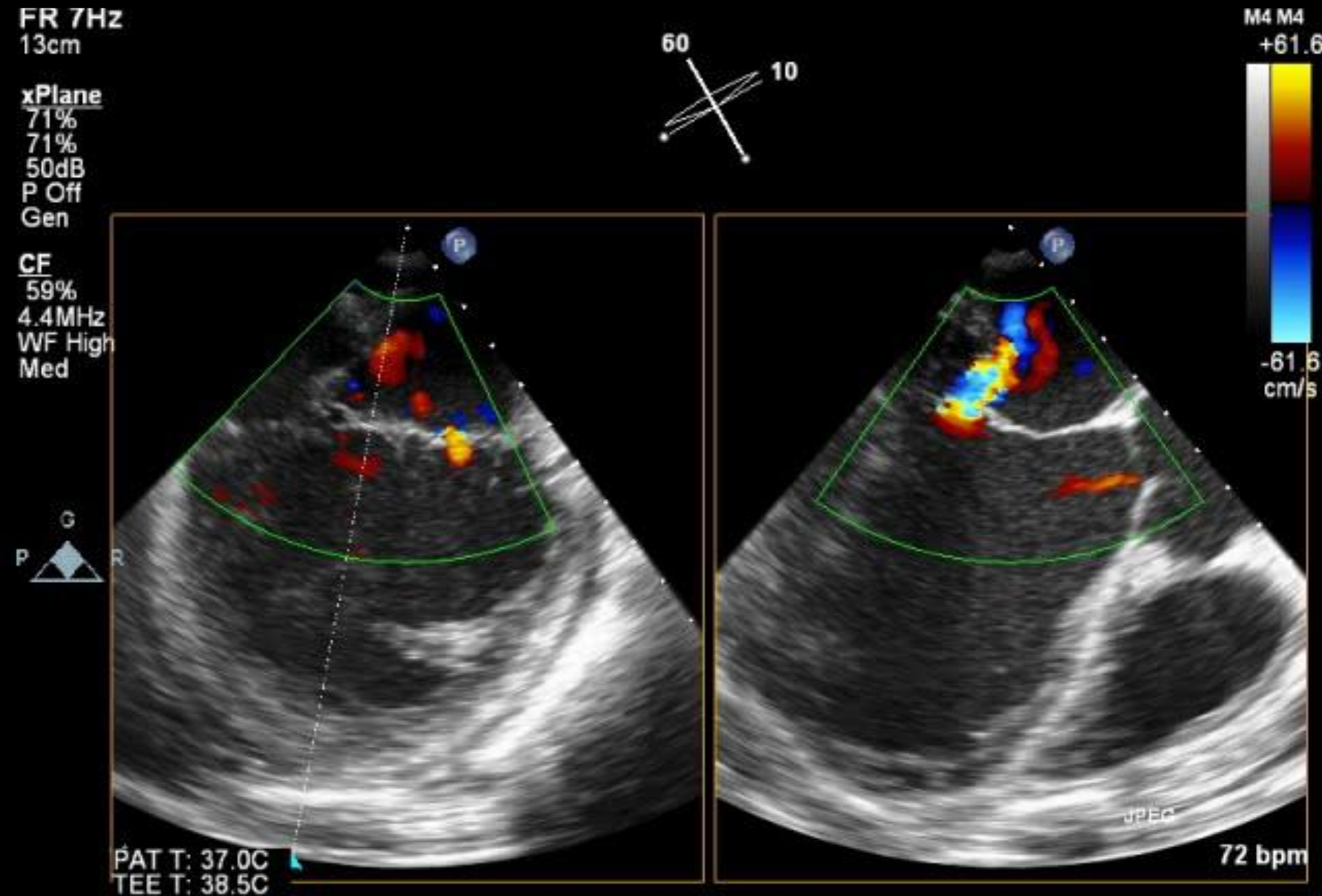
69%
69%
50dB
P Off
Gen
60
14
M4
G
P
R
PAT T: 37.0C
JPEG
73 bpm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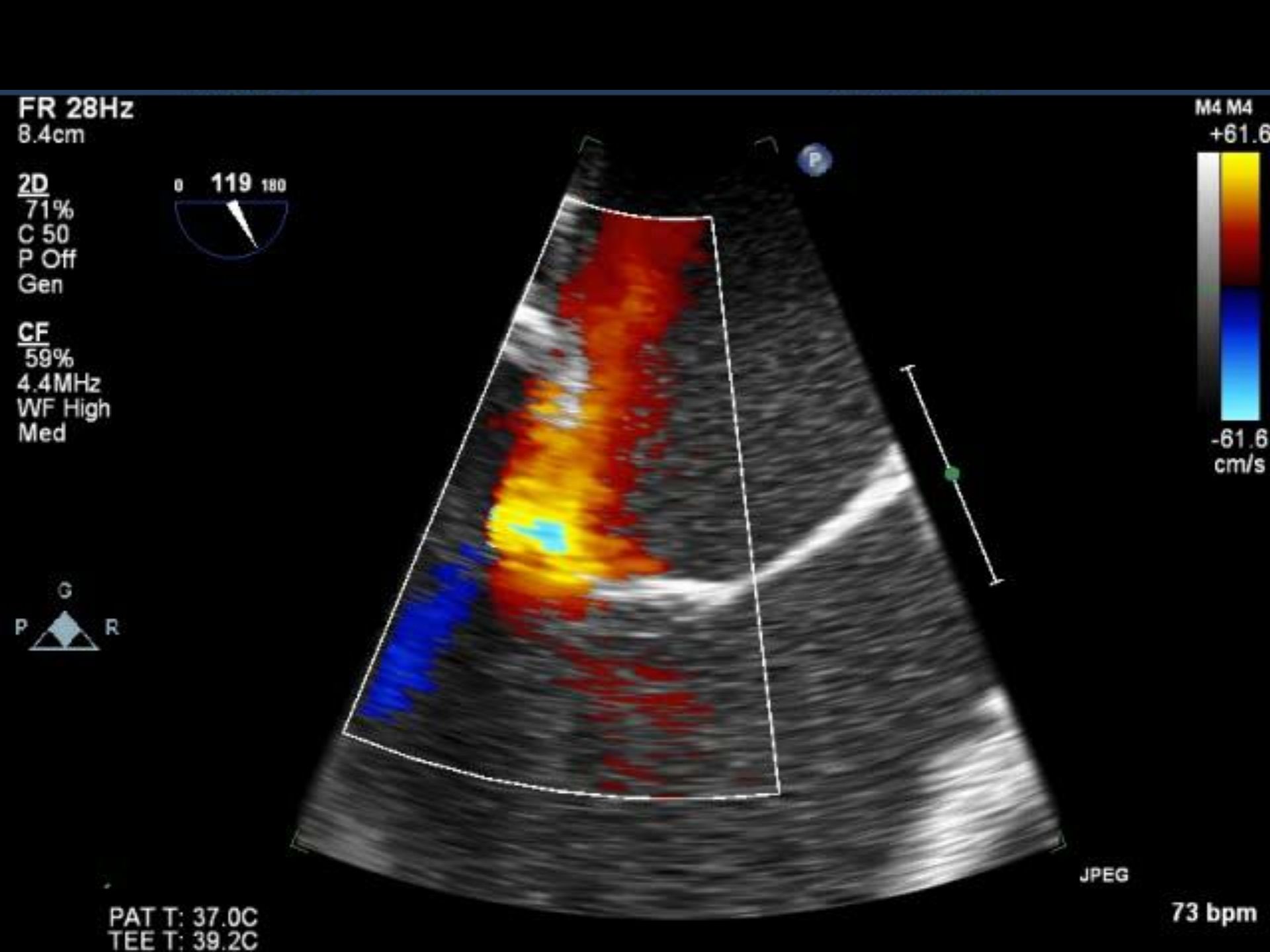
13cm
xPlane
71%
71%
50dB
P Off
Gen
CF
59%
4.4MHz
WF High
Med
60
10
M4 M4
+61.6
-61.6
cm/s
P
R
PAT T: 37.0C
TEE T: 38.5C
72 bpm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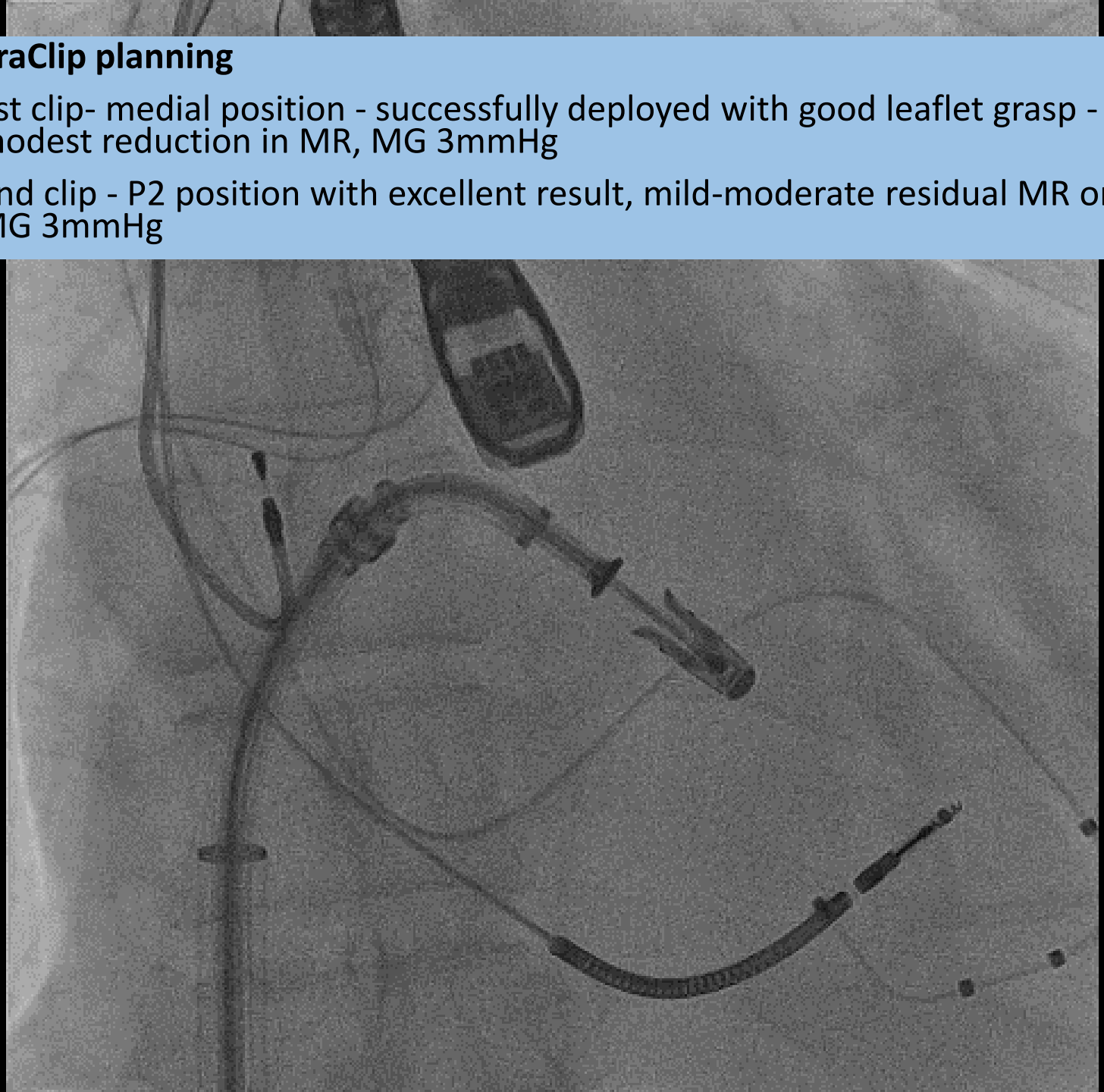
8.4cm
2D
71%
C 50
P Off
Gen
0
119
180
CF
59%
4.4MHz
WF High
Med
M4 M4
+61.6
-61.6
cm/s
G
P
R
JPEG
PAT T: 37.0C
TEE T: 39.2C
73 bpm

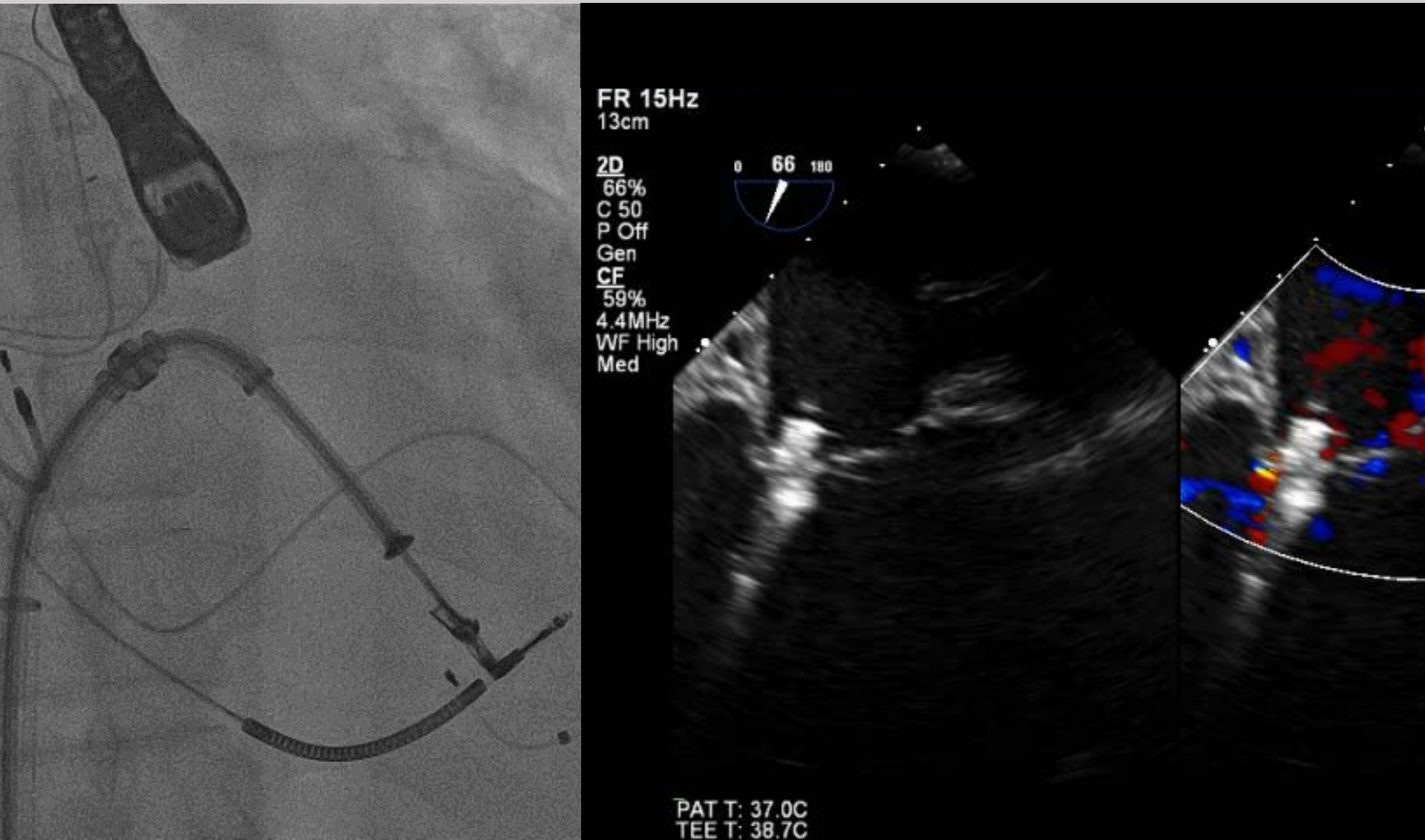

FR 10Hz
7.6cm
3D Beats 1
M4
3D
3D 47%
3D 40dB
0
50
180
anterolateral
A1
P1
A2
A3
P2
P3
posteromedial
JPEG
PAT T: 37.0C
TEE T: 39.5C
71 bpm



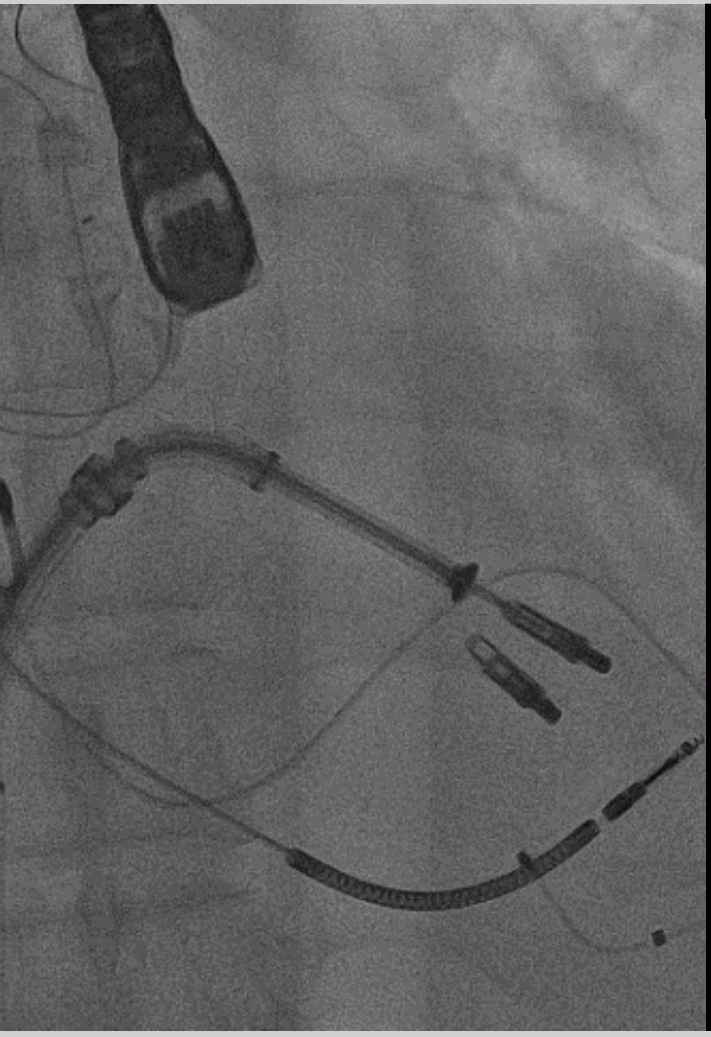
MitraClip planning

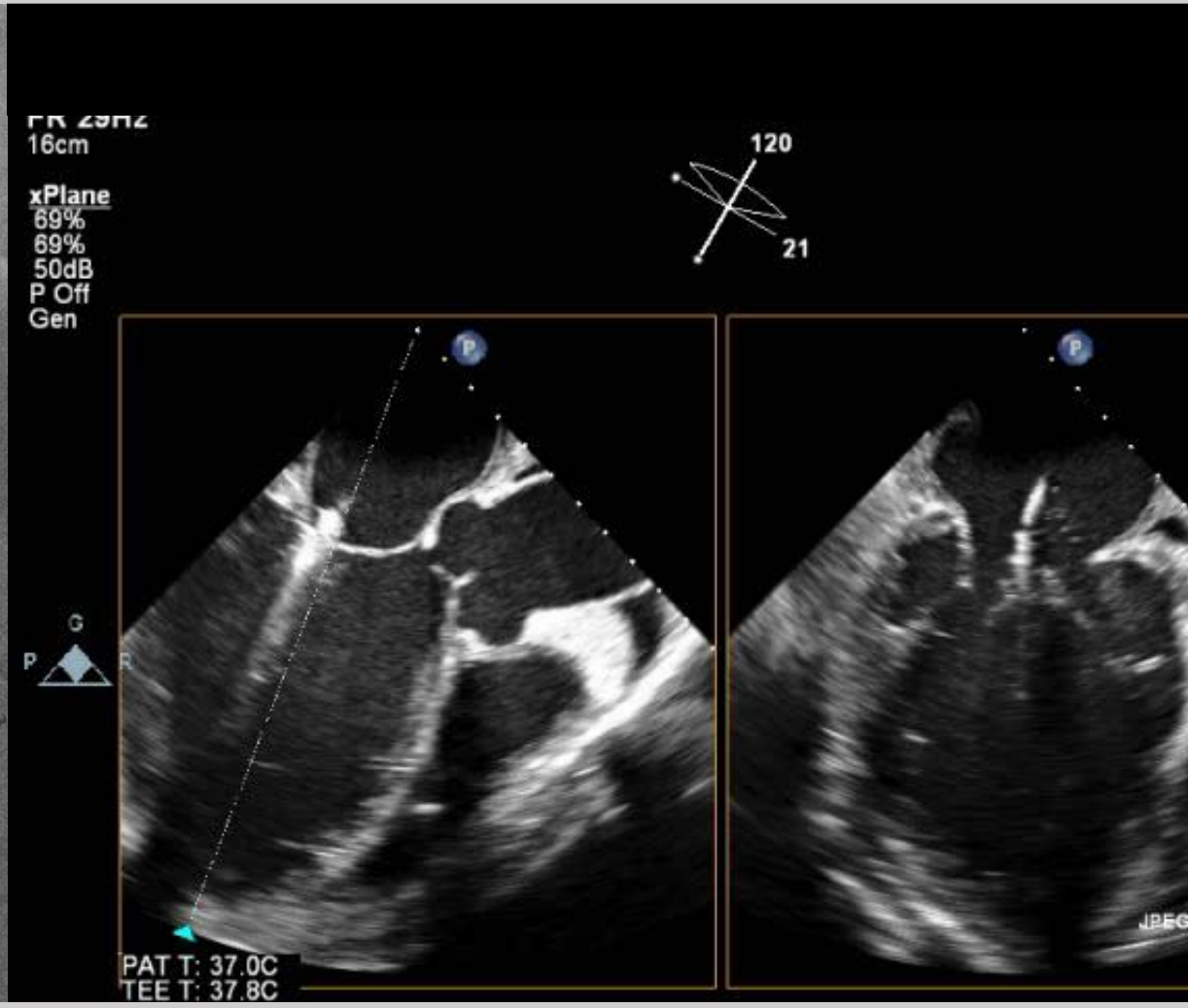
- 1st clip- medial position - successfully deployed with good leaflet grasp - modest reduction in MR, MG 3mmHg
- 2nd clip - P2 position with excellent result, mild-moderate residual MR only, MG 3mmHg

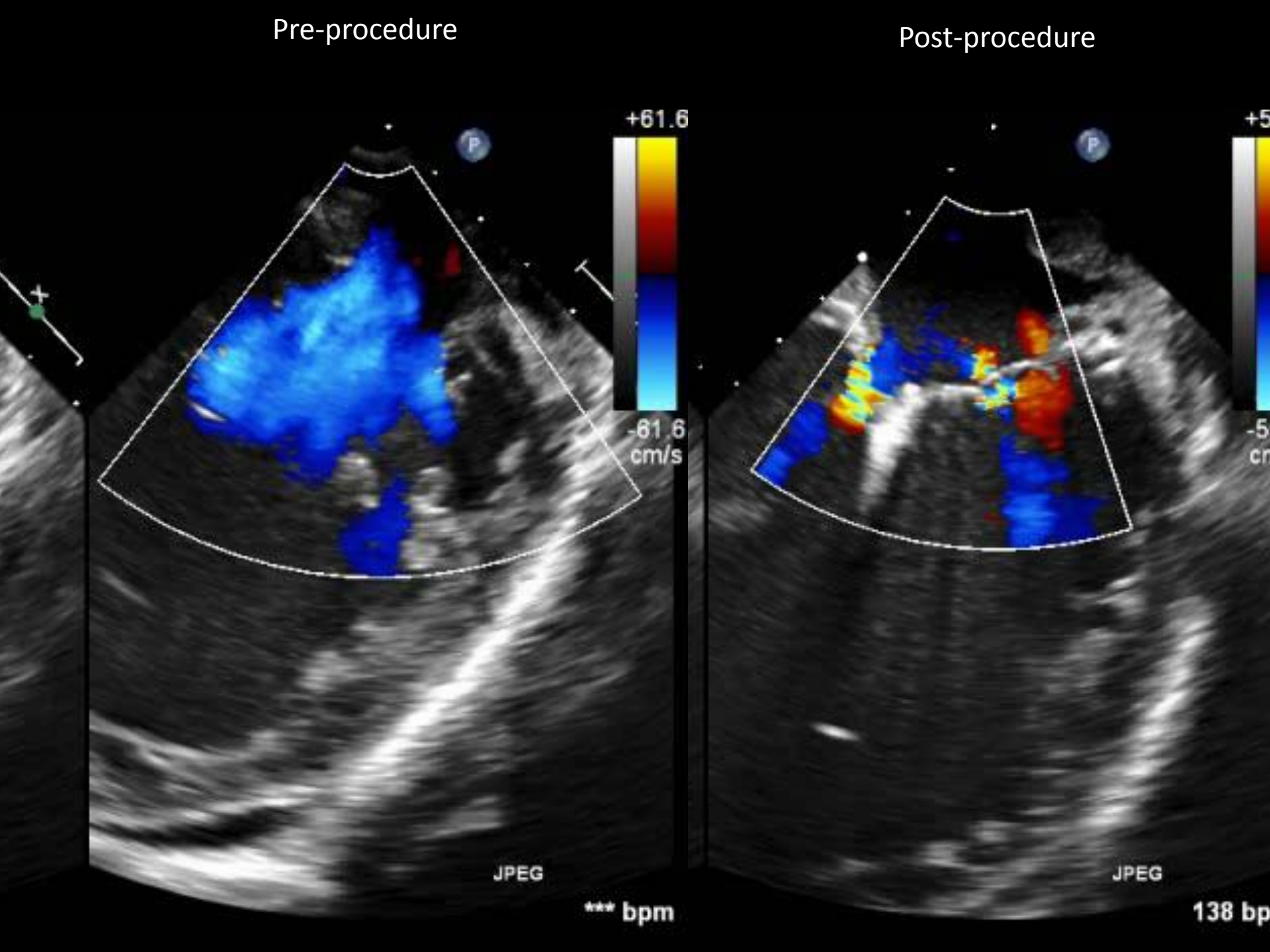
Medial clip deployment



2nd Clip Deployment

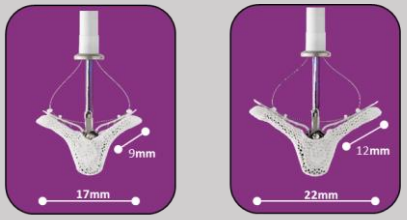





Pre-procedure
Post-procedure
+61.6
-61.6
cm/s
JPEG
*** bpm
JPEG
138 bp


8.4cm
3D
3D 47%
3D 40dB
0
60
180
JPEG

Global EXPAND Study

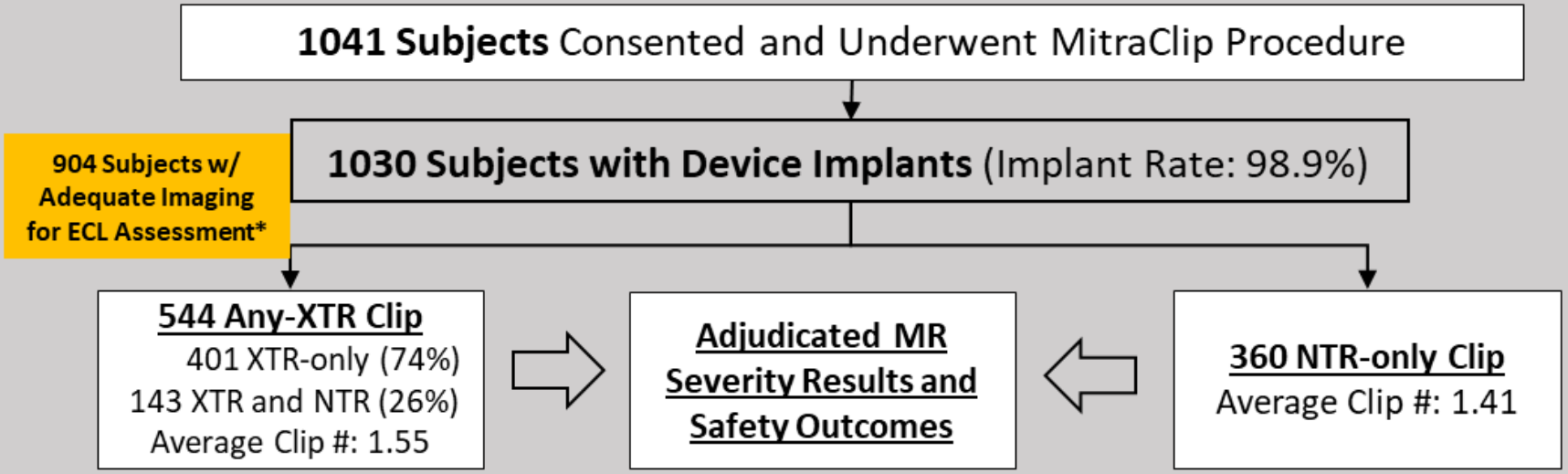


MitraClip NTR MitraClip XTR

- Abbott introduced an additional implant size with the MitraClip NTR and XTR Systems in 2018, and initiated Global EXPAND study to evaluate real world clinical experience.
- EXPAND Steering committee provided clip selection recommendations based on following anatomical considerations.

	Anatomical Consideration	Favors XTR	Favors NTR
Leaflet insertion	Longer Leaflet	+	
	A2-P2	+	
	Large Flail	+	
	Redundant Leaflet	+	
	Short Restricted Leaflet		+
Tissue Quality	Calcification of annulus and leaflet		+
Gradient	Smaller MV area		+
Chordal entrapment	Mitral Valve commissures		+

Global EXPAND Study



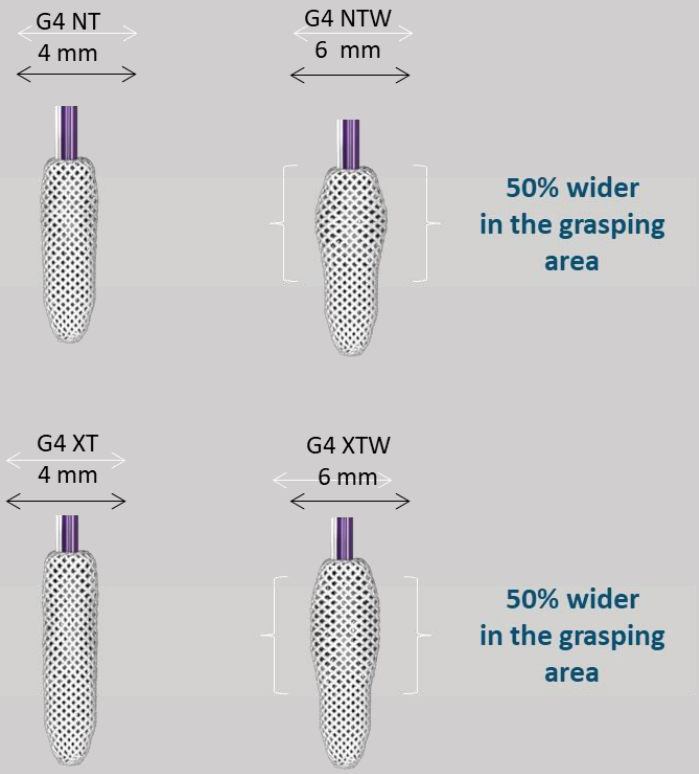
*106 Subjects with Missing Baseline Images from Sites and 20 Subjects with not evaluable Baseline MR by ECL excluded from analysis. 69 Subjects with not evaluable MR etiology by ECL excluded from analysis results for subjects with primary MR and secondary MR.

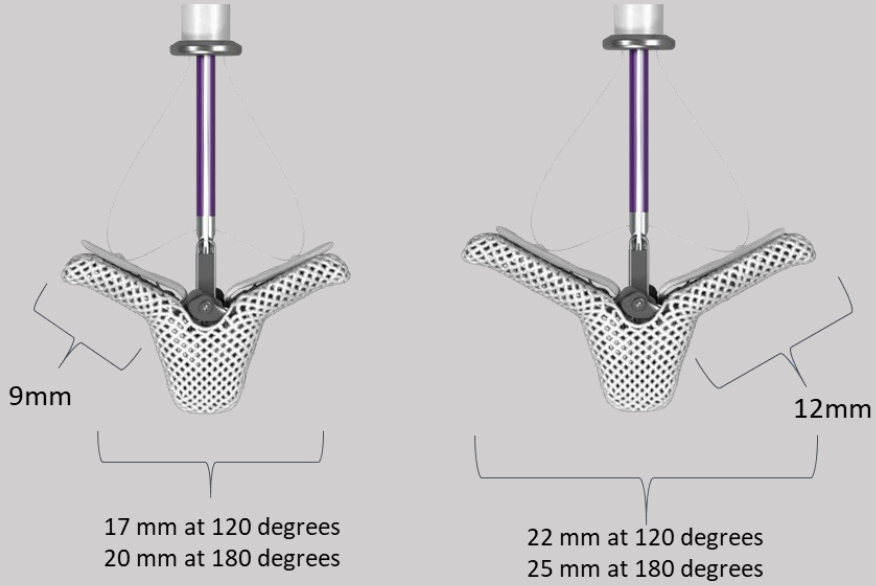
Methods

Subgroup analysis performed to assess the association between MV anatomic variables (39 echo measures) and clinical outcomes for each clip type:

- Reduction of MR Severity by at least ≥ 2 Grades
- Major adverse events (MAE) and Leaflet Adverse Events (LAE)

MitraClip G4





Courtesy: Abbott Structural

MitraClip G4

Both Grippers Lowered

One Gripper Lowered

Courtesy: Abbott Structural

Cardioband [Edwards Lifesciences]

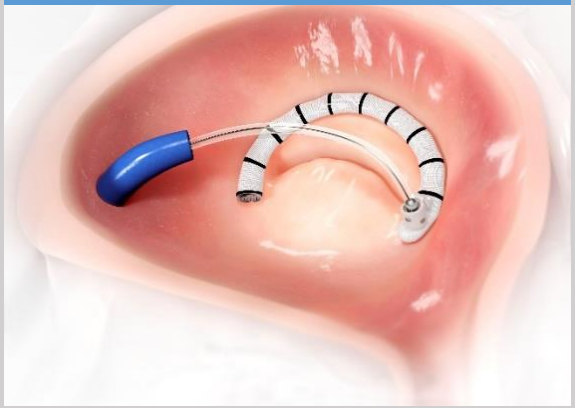
Edwards Cardioband

Direct Annuloplasty

Cardioband Mitral System

Key Features

- Annular Reduction

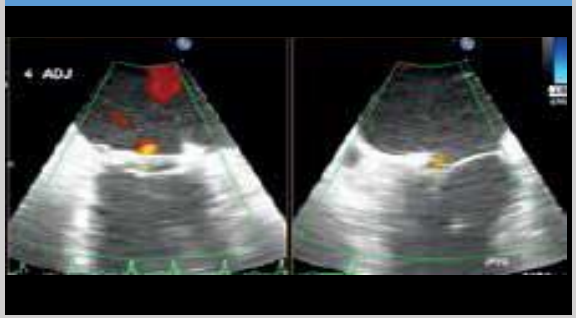


- Restores valve to a more
- functional state, facilitating
- leaflet coaptation - reducing MR

- Adjustable Implantation

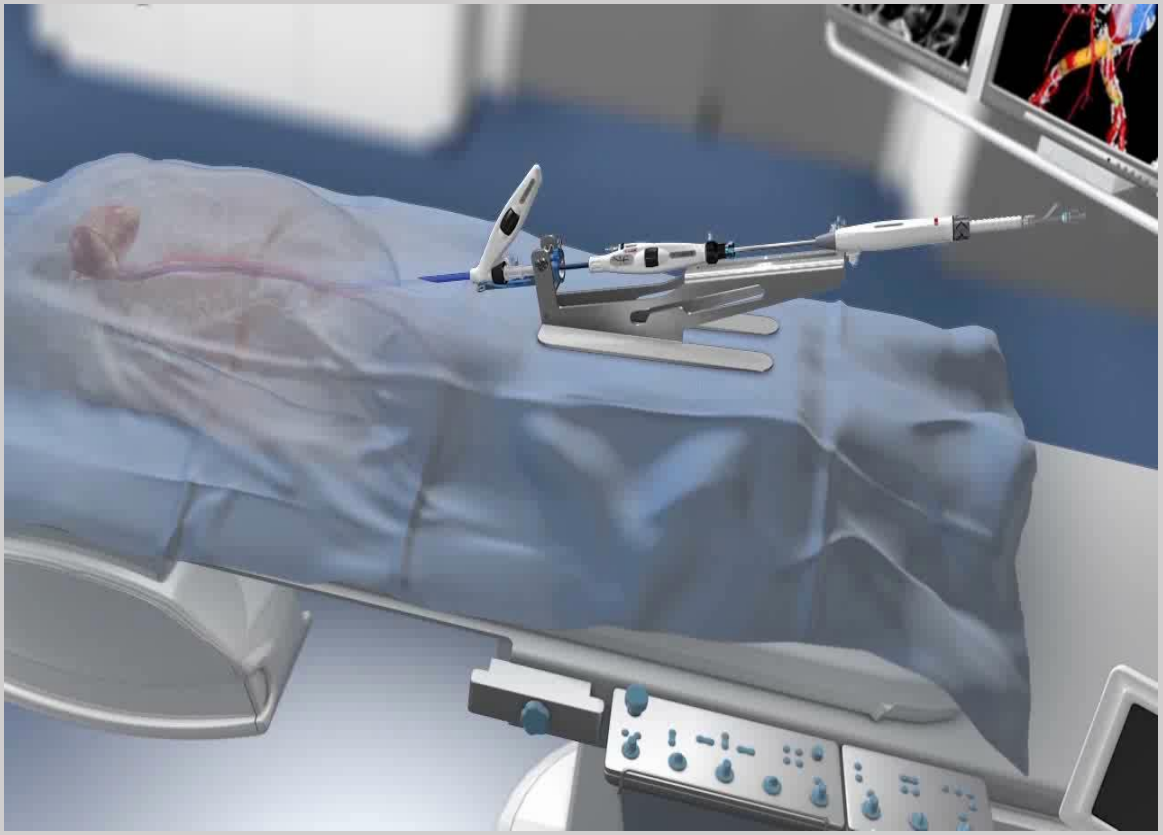
- Enables annular reduction based on each patient's anatomy

- Real-Time Confirmation



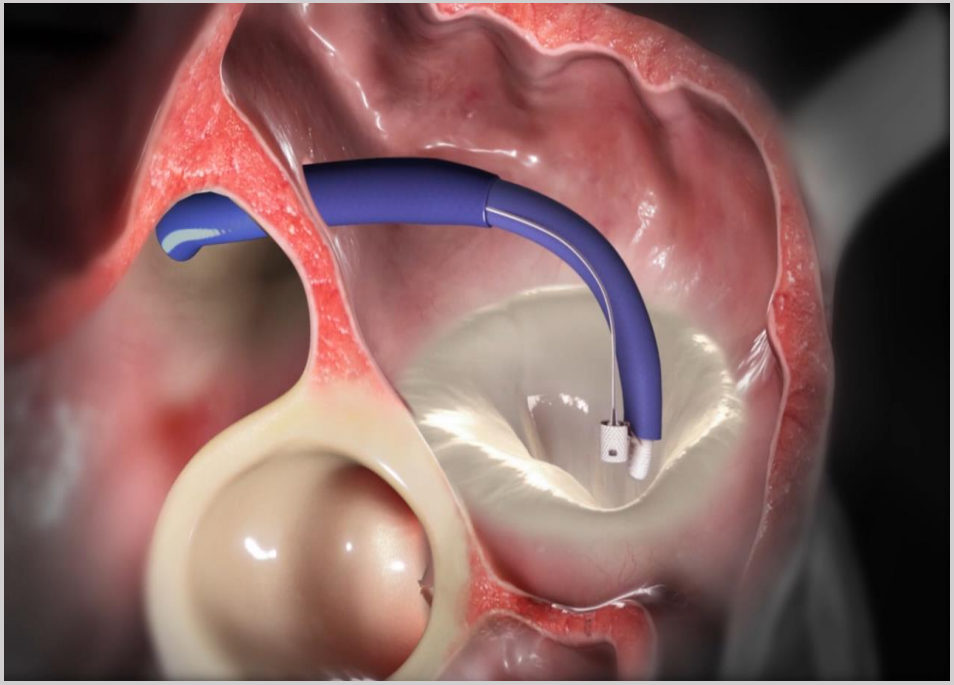
- Allows real-time adjustment and confirmation of MR reduction

Cardioband Procedure

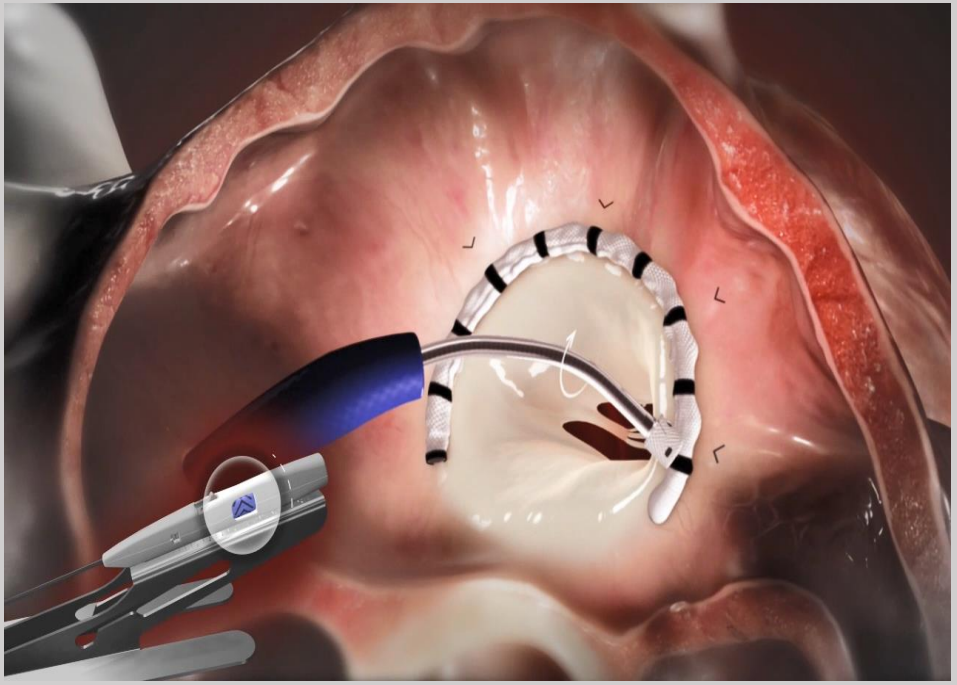


Access via transseptal puncture & system insertion

Cardioband Procedure



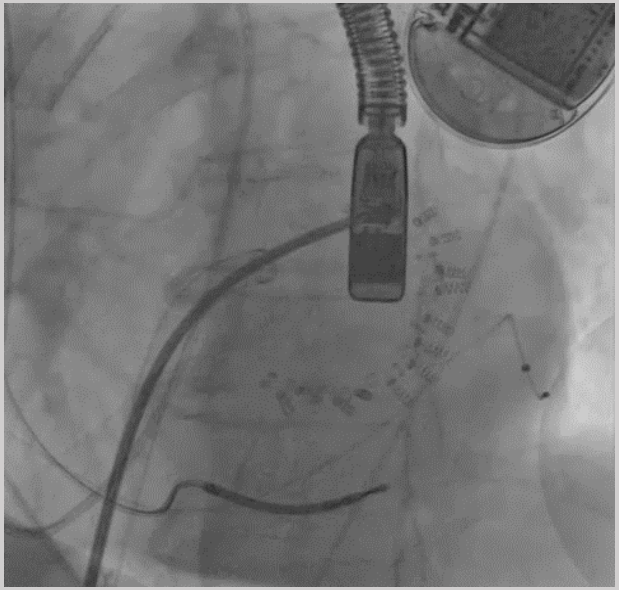
Deploy implant via steerable catheter

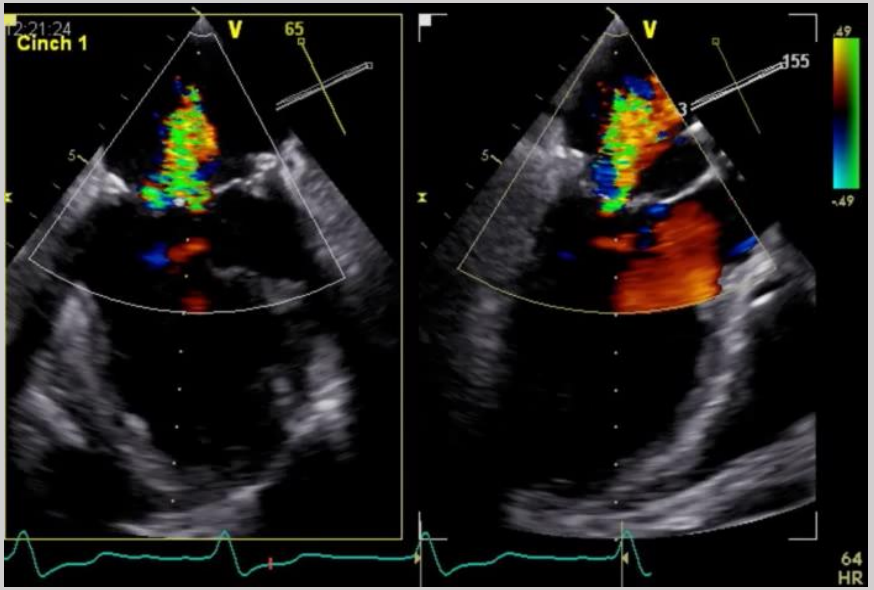


Adjust and confirm real-time reduction of MR

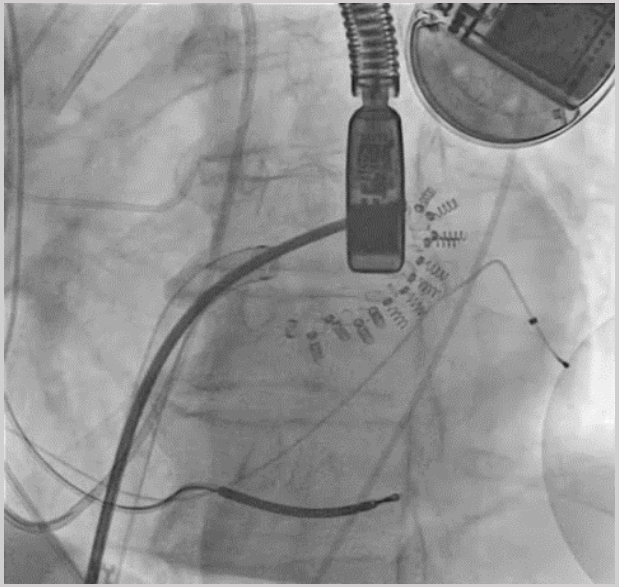
Adjustment in Cinching Force

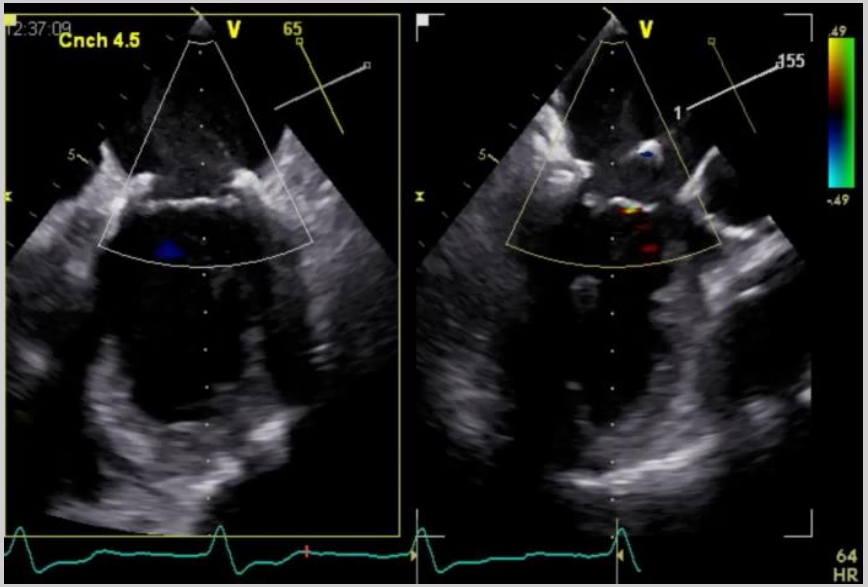
Pre-adjustment





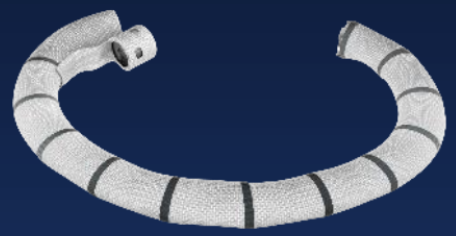
Final adjustment





Edwards Cardioband

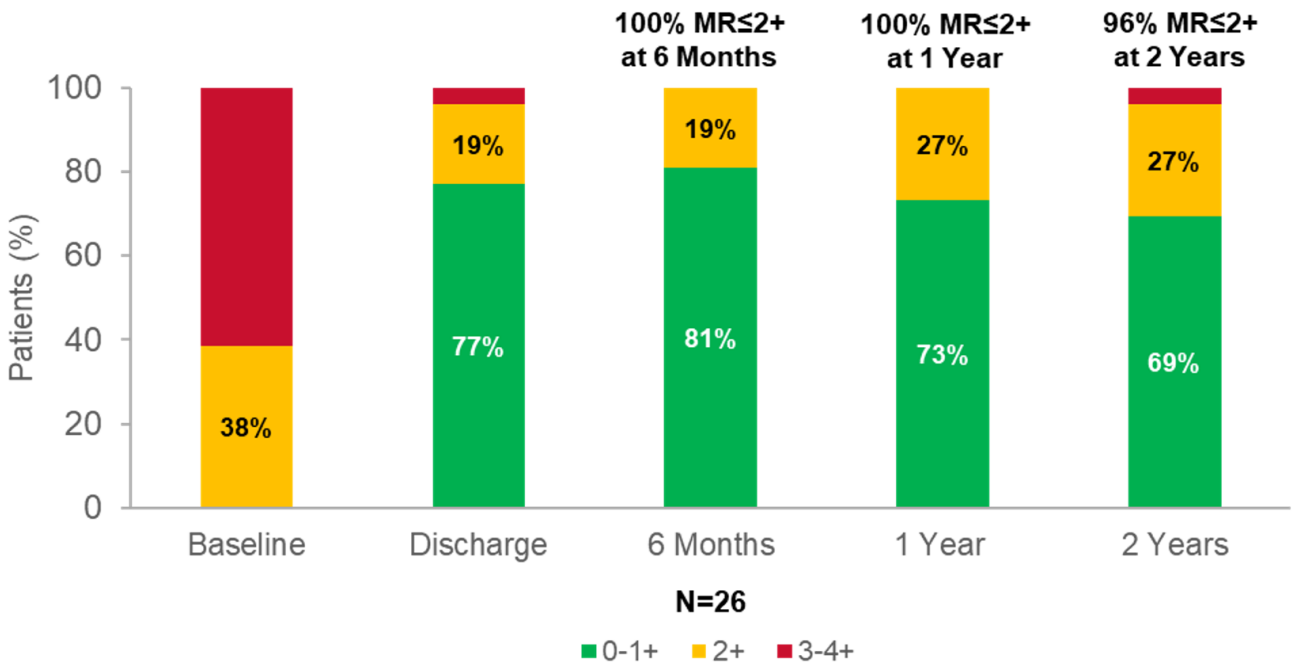
- 6 sizes
- CT assessment of annulus size



Cardioband Implant	Mitral Valve posterior annular circumference commissure to commissure (mm)	Max. Number on the Adjustment counter window
A	73-80	3.5
B	81-88	4
C	89-96	4.5
D	97-104	5
E	105-112	5.5
F	113-120	5.5

MR Reduction Sustained at 2 Years[1]

Paired Analysis



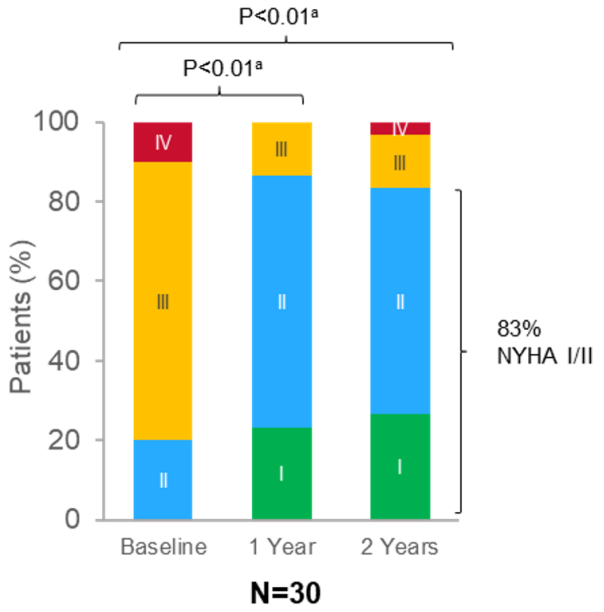
[1]Core Lab - Dr. Paul Grayburn – Baylor University

95% MR ≤ 2+ at 1 year, sustained at 2 years (core lab evaluated)
87% survival at 1 year
No mitral stenosis

Clinically Significant Improvements at 2 Years

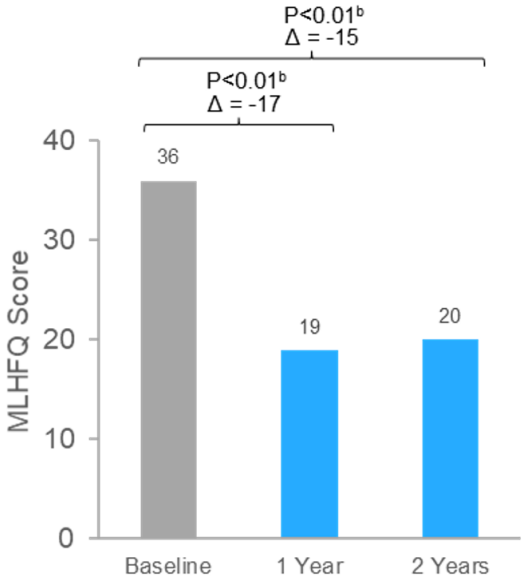
Paired Analysis

NYHA Class



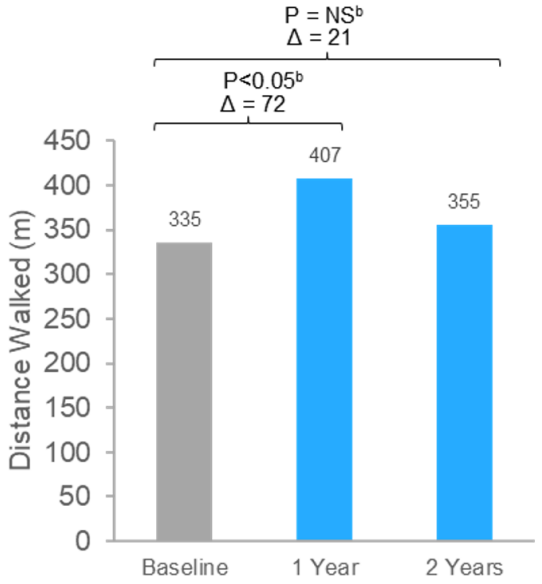
N=30

MLHFQ Score



N=27

6MWT



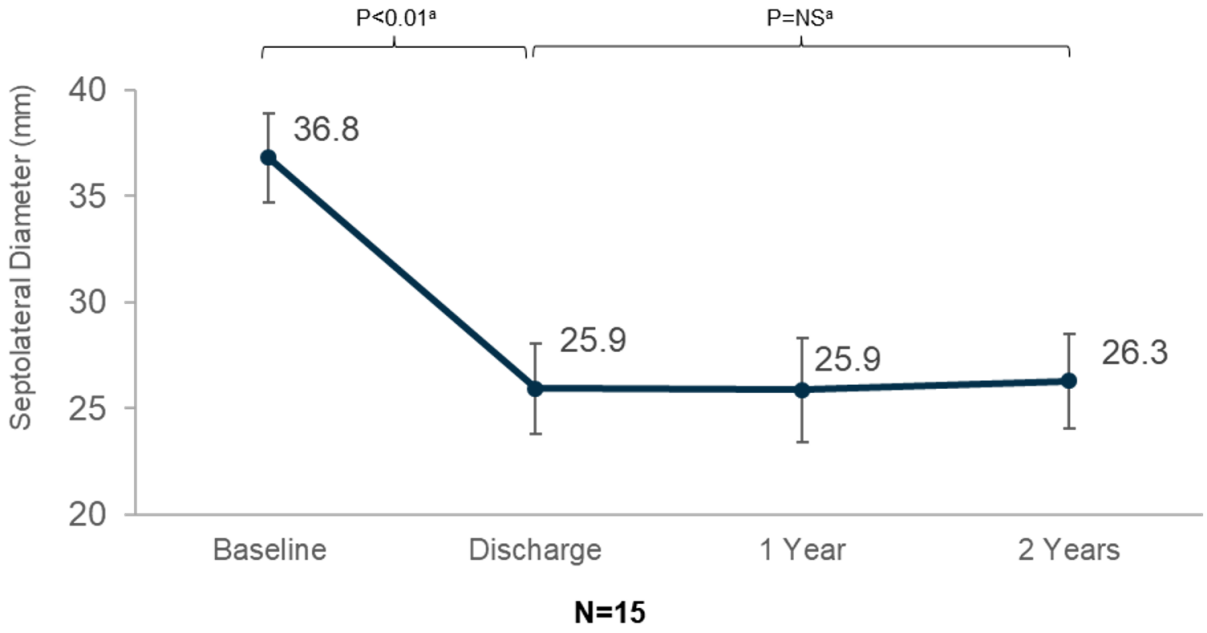
N=18

[a]McNemar's test
[b]T-test
6MWT – Six Minute Walk Test; MLHFQ – Minnesota Living With Heart Failure Questionnaire; NYHA – New York Heart Association

Clinically significant improvements in functional status, quality of life and exercise capacity at 1 year, sustained at 2 years

29% Annular Reduction Sustained at 2 Years[1]

Paired Analysis



[1]Core Lab - Dr. Paul Grayburn – Baylor University
[a]ANOVA T-test

Pascal [Edwards Lifesciences]

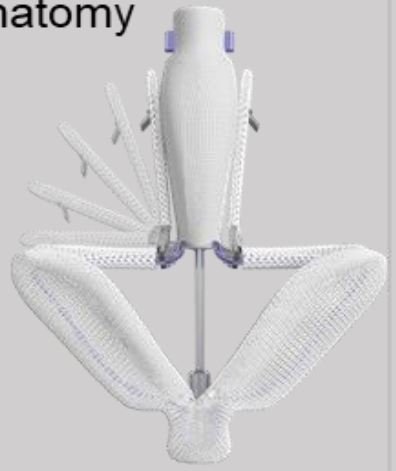
Edwards PASCAL Transcatheter Valve Repair System

Central spacer

A unique central spacer is designed to reduce leaflet stress and **fill regurgitant gap** to minimise MR

Independent leaflet grasping

Independent actuation and a distinct clasp design allow **leaflet capture precision** while respecting native anatomy

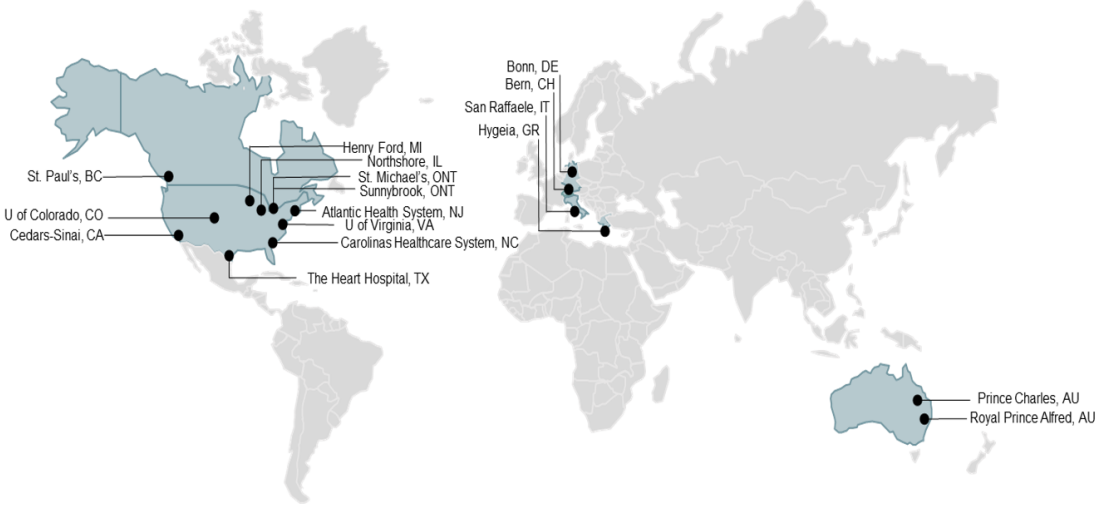


Device elongation

Device elongation feature **optimizes subvalvular manoeuvrability** and promotes procedure safety

Single arm, multicenter, prospective study to evaluate the safety, performance, and clinical outcomes of the PASCAL Transcatheter Valve Repair System for clinically significant mitral regurgitation

THE CLASP STUDY



Inclusion criteria

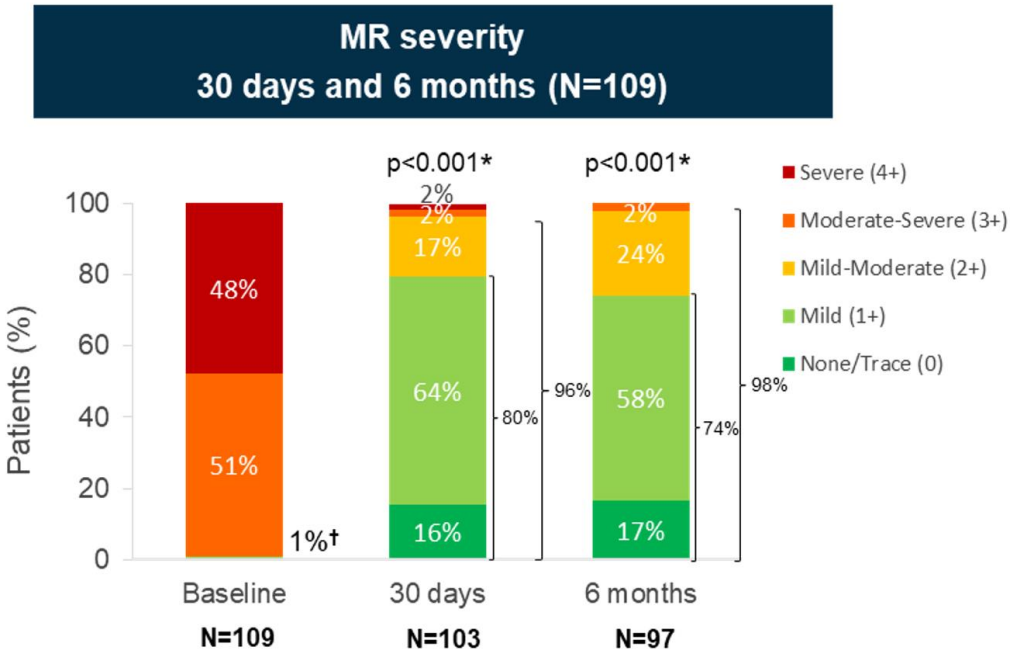
- Age ≥ 18 years
- NYHA functional Class ≥ II despite optimal therapy
- Clinically significant mitral regurgitation (moderate-to-severe or severe mitral regurgitation) confirmed by echocardiography
- The primary regurgitant jet is non-commissural

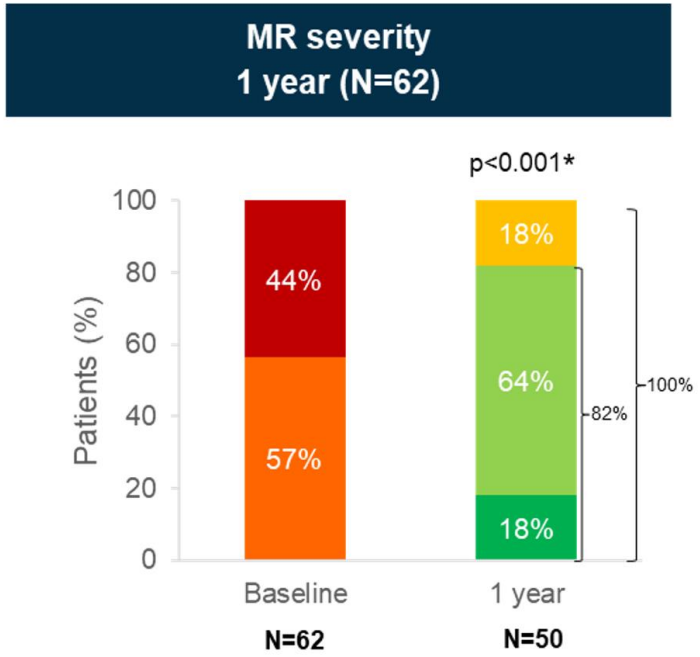
Exclusion criteria

- Mitral valve area < 4.0 cm²
- Left ventricular ejection fraction < 20%
- Right-sided CHF or echo evidence of severe RV dysfunction
- Life expectancy of less than 12 months

MR at 6 Months and 1 Year by TTE (Core Lab)[1]

100% of patients MR ≤2+ and 82% MR ≤1+ sustained at 1 year



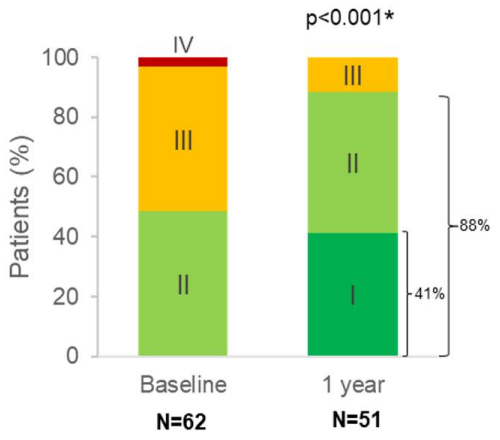


[1]TTE; Cardiovascular Core Lab at Morristown Medical Center, Morristown, NJ, USA. *P-values calculated using Wilcoxon signed rank test; Paired analysis comparing baseline vs. 30 days (n=102), baseline vs. 6 months (n=96), or baseline vs. 1 year (n=50). †One patient had MR 1+ by TTE although 3+ by TEE

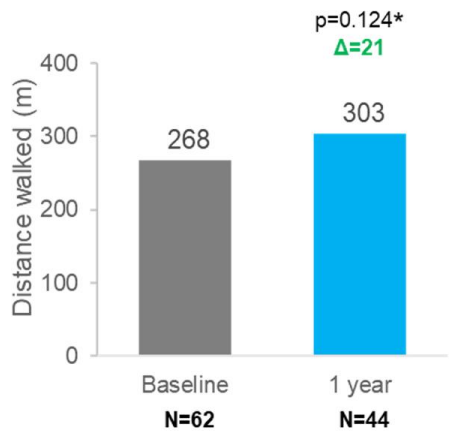
THE CLASP STUDY

Benefits Sustained at 6 Months and 1 Year

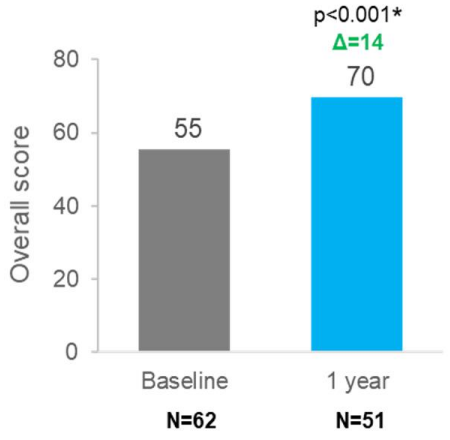
NYHA
1 year (N=62)



6MWD
1 year (N=62)



KCCQ
1 year (N=62)

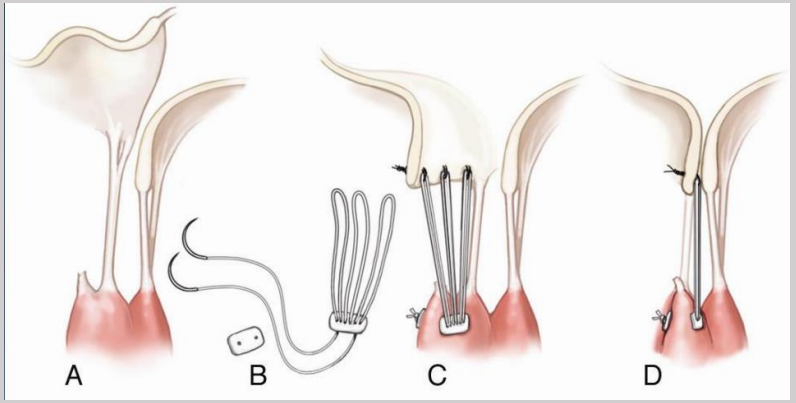


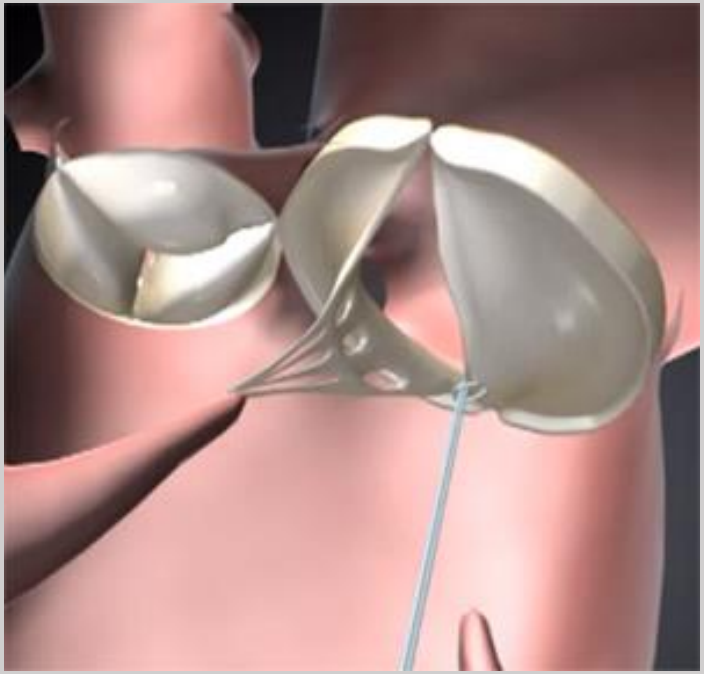
*P-values calculated using Wilcoxon signed rank test or paired t-test; NYHA paired analysis compares baseline vs. 1 year (n=51); KCCQ paired analysis compares baseline vs 1 year (n=51); 6MWD paired analysis compares baseline vs 1 year (n=44). Δ is the difference between baseline and corresponding timepoints. NYHA=New York Heart Association; 6MWD=Six minute walk distance; KCCQ=Kansas City Cardiomyopathy Questionnaire

Neochord [Neochord Inc]

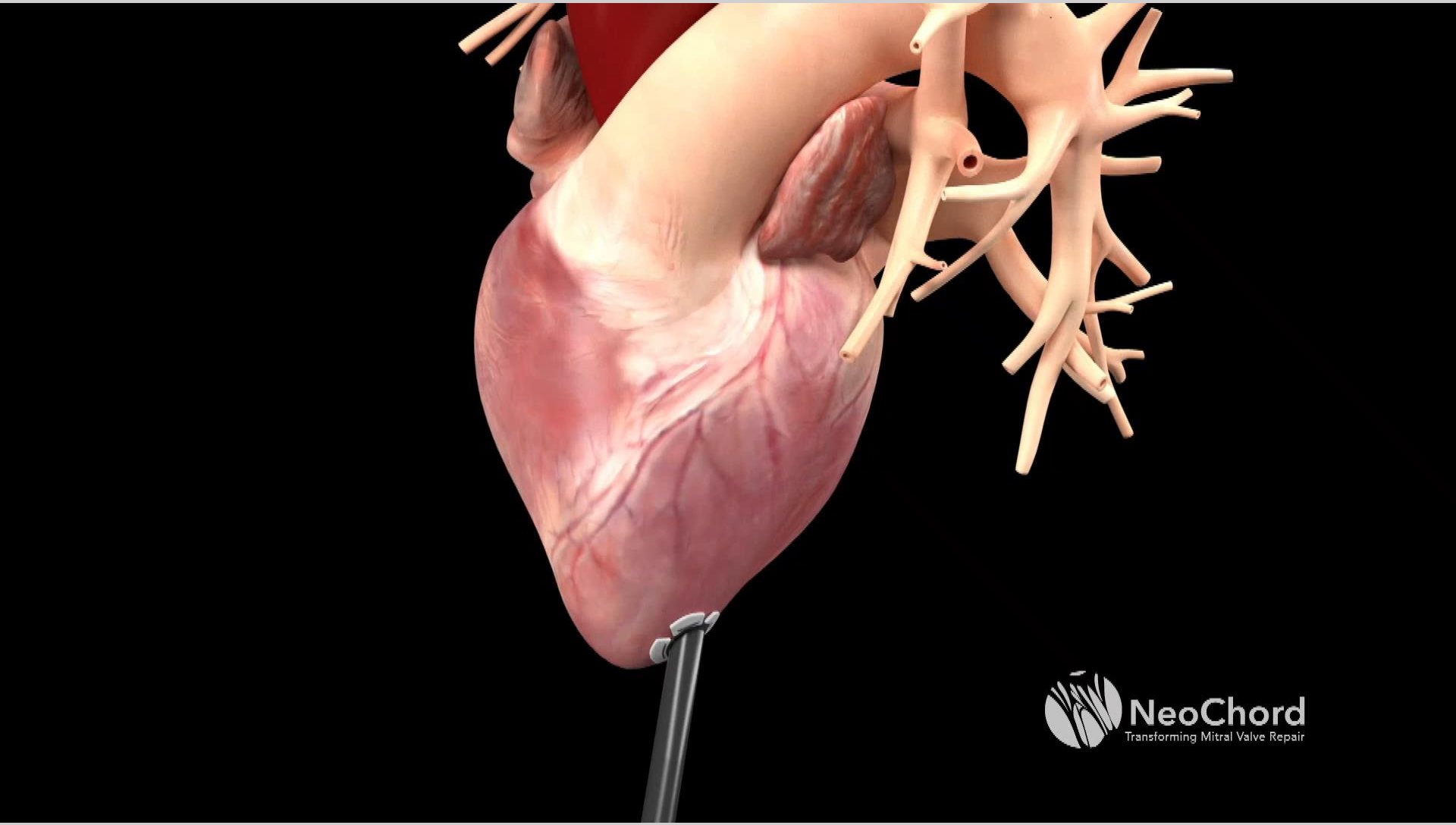
NeoChord DS100

- Artificial chord implantation
- ePTFE material
- Transpical system

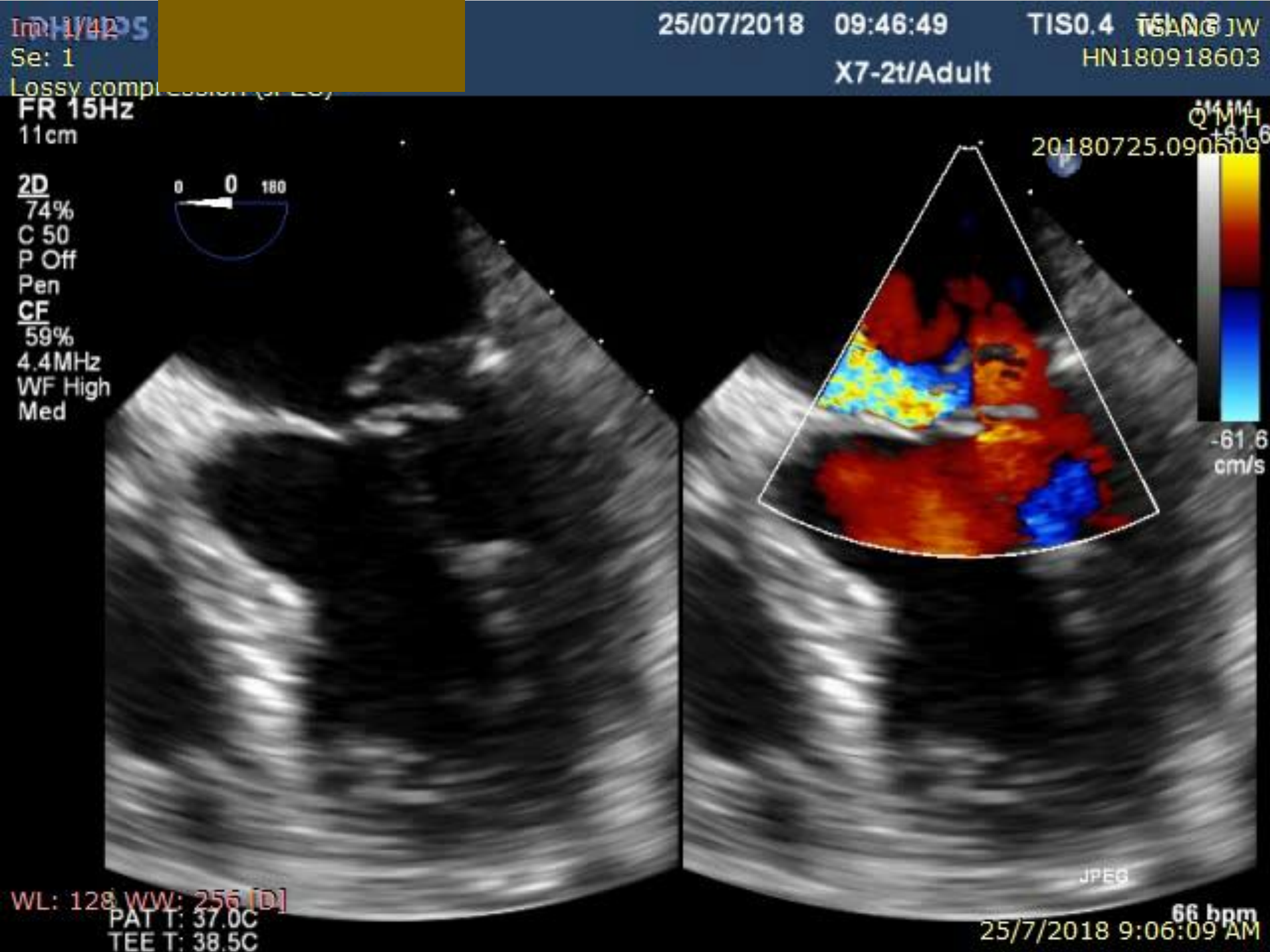




NeoChord
Transforming Mitral Valve Repair



Neochord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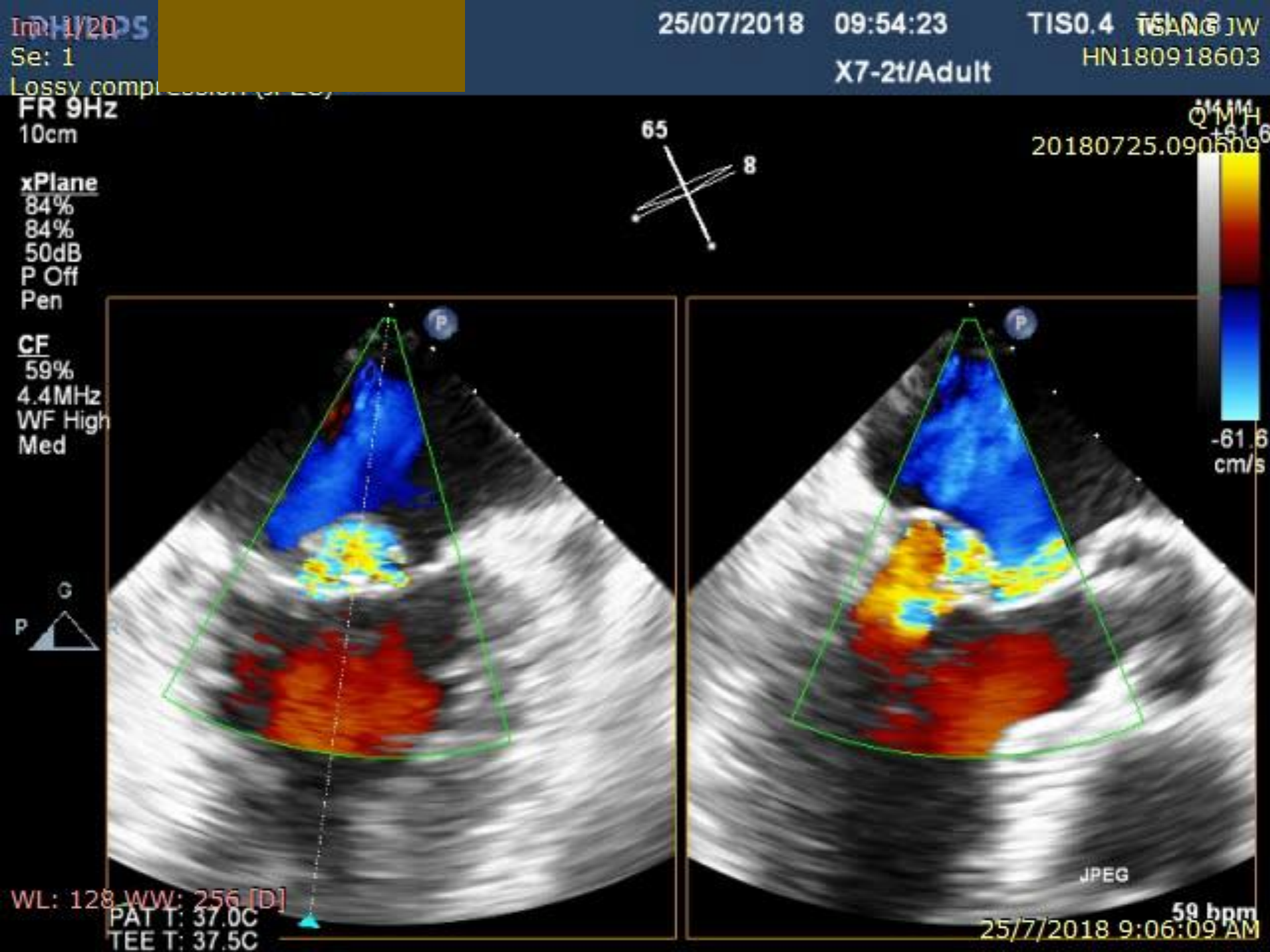
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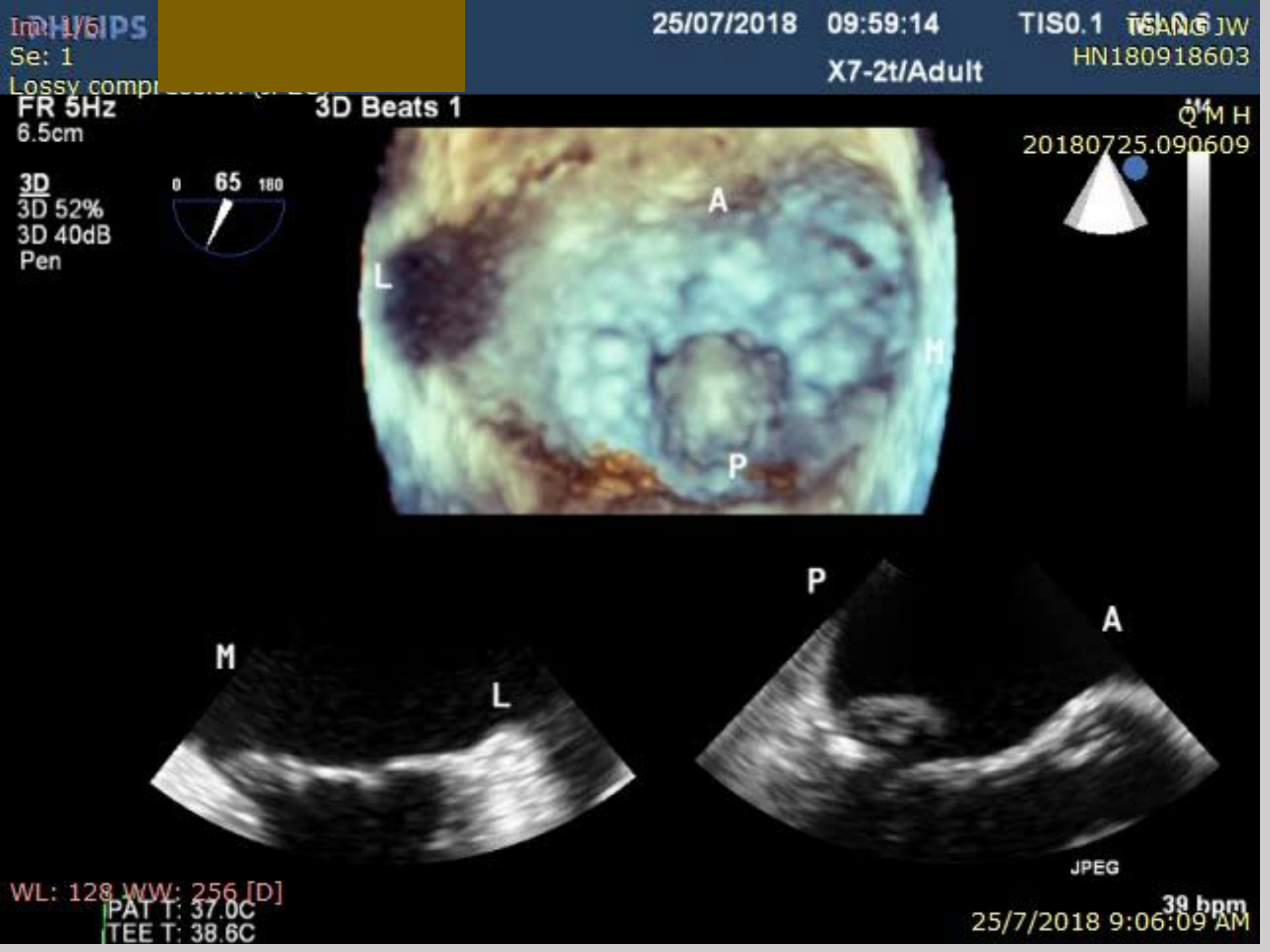
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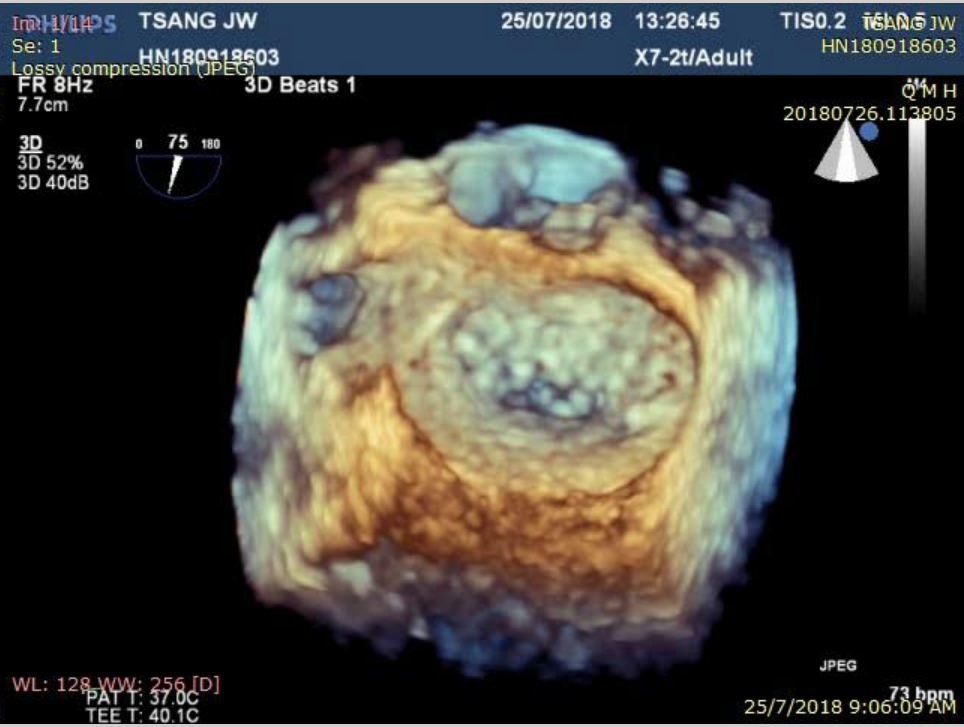
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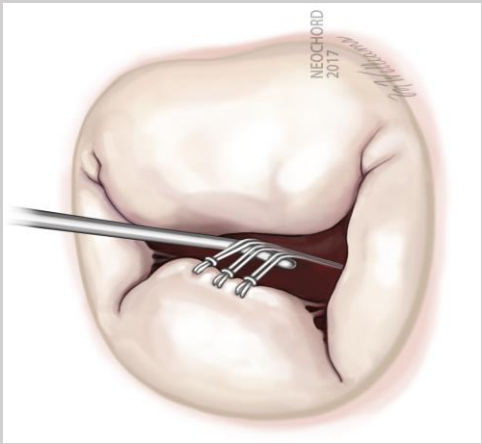
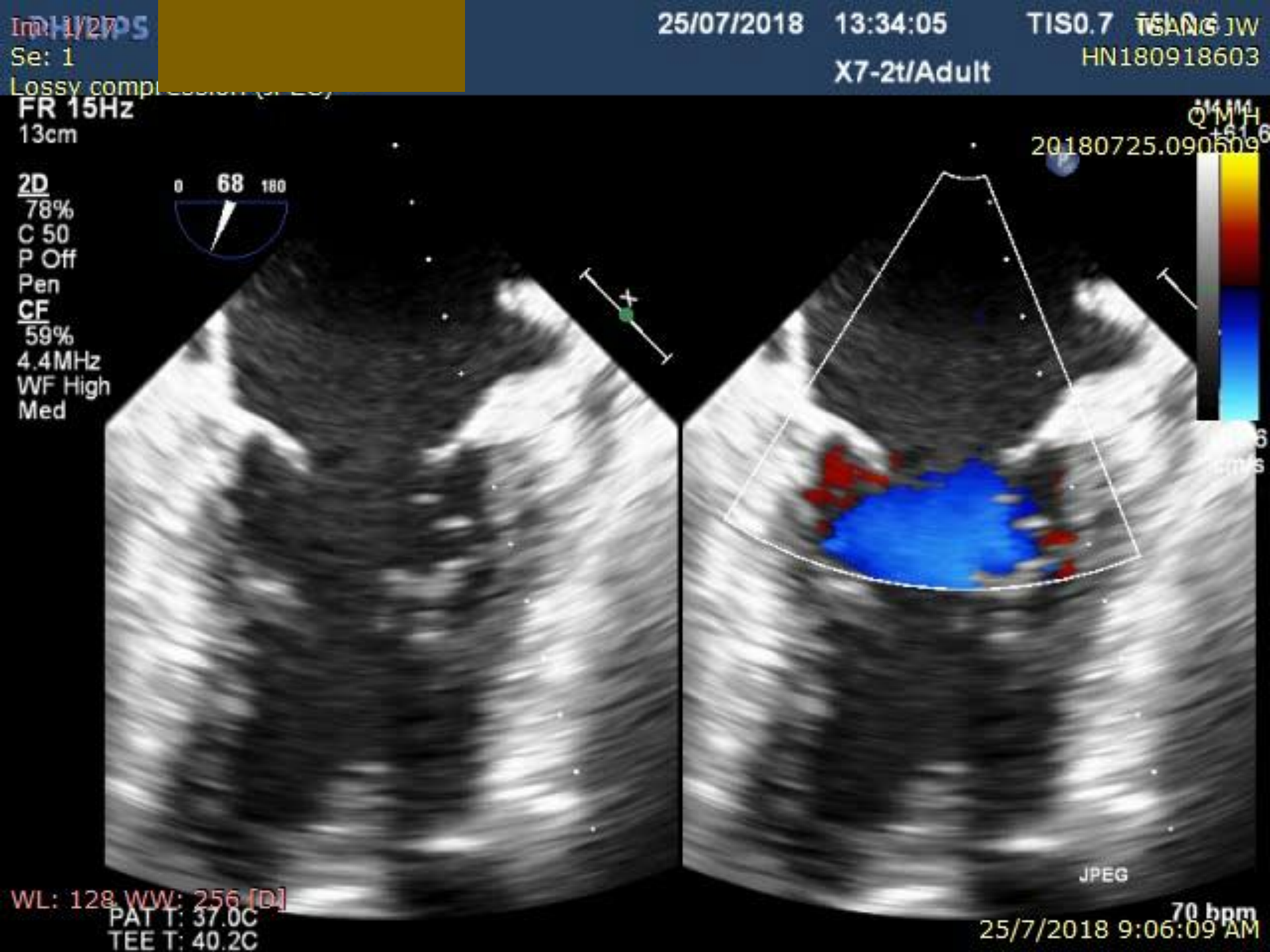

NEOCHORD
2017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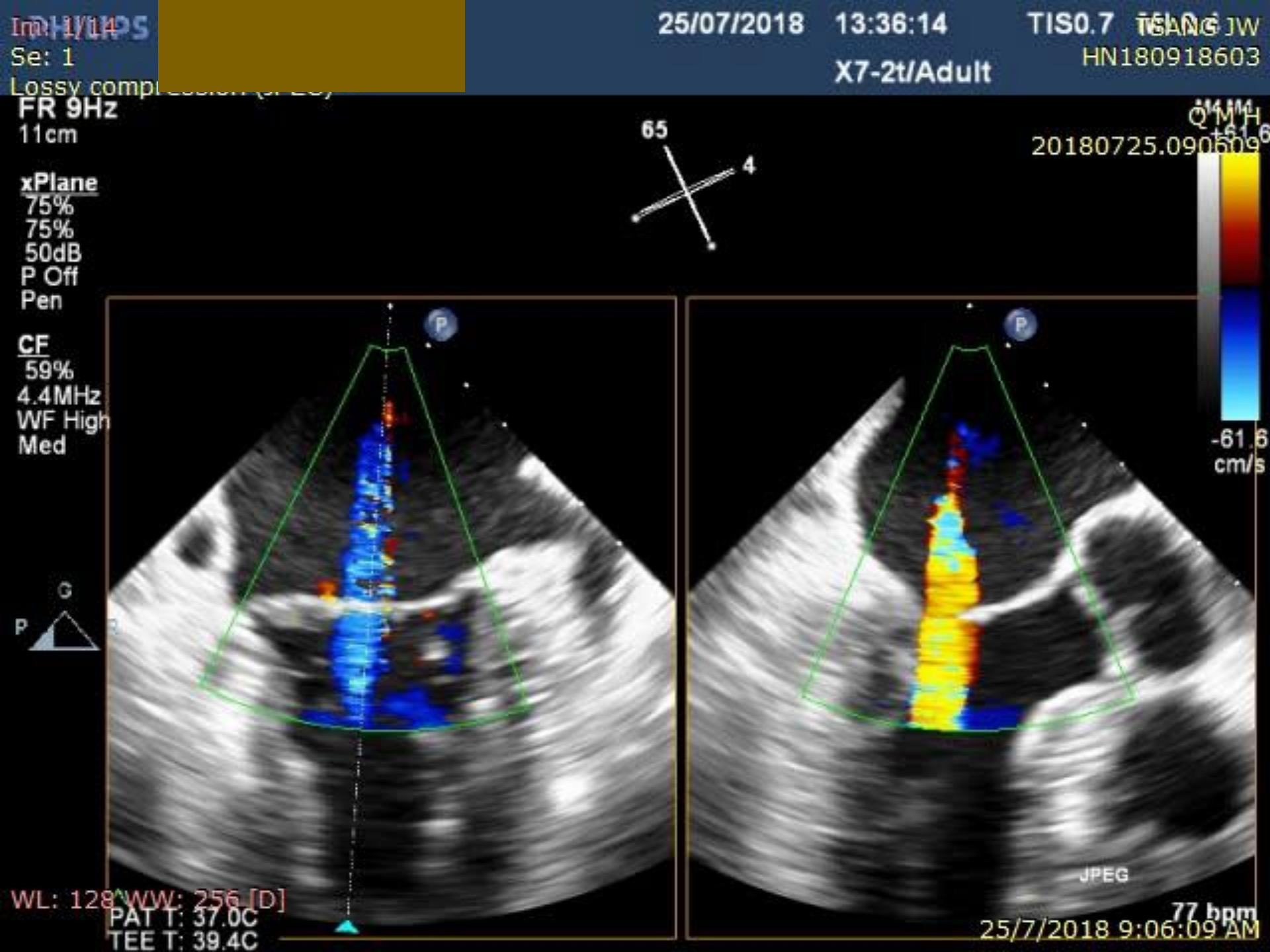
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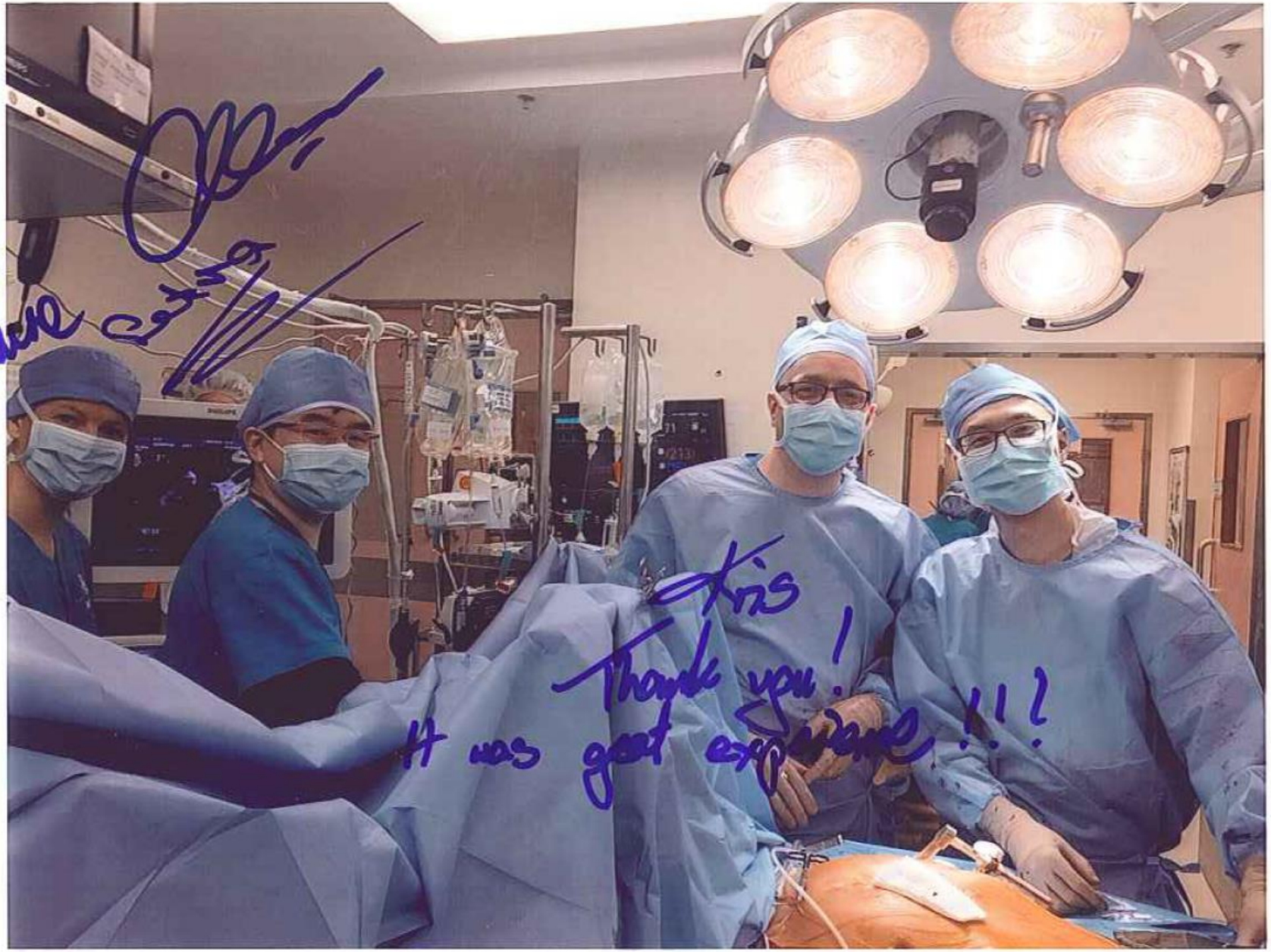

Thank you!
It was great experience !!!

Arto System [MVRx]

The ARTO System

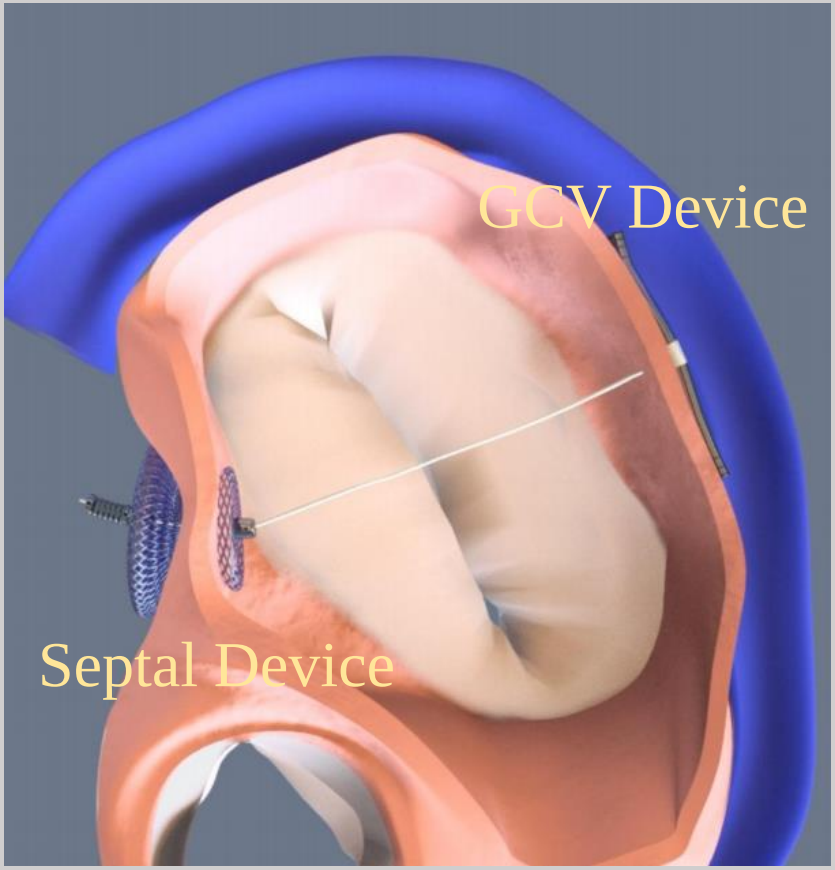
***Immediate and direct* A-P diameter shortening** to treat functional mitral regurgitation

No compression of left circumflex artery

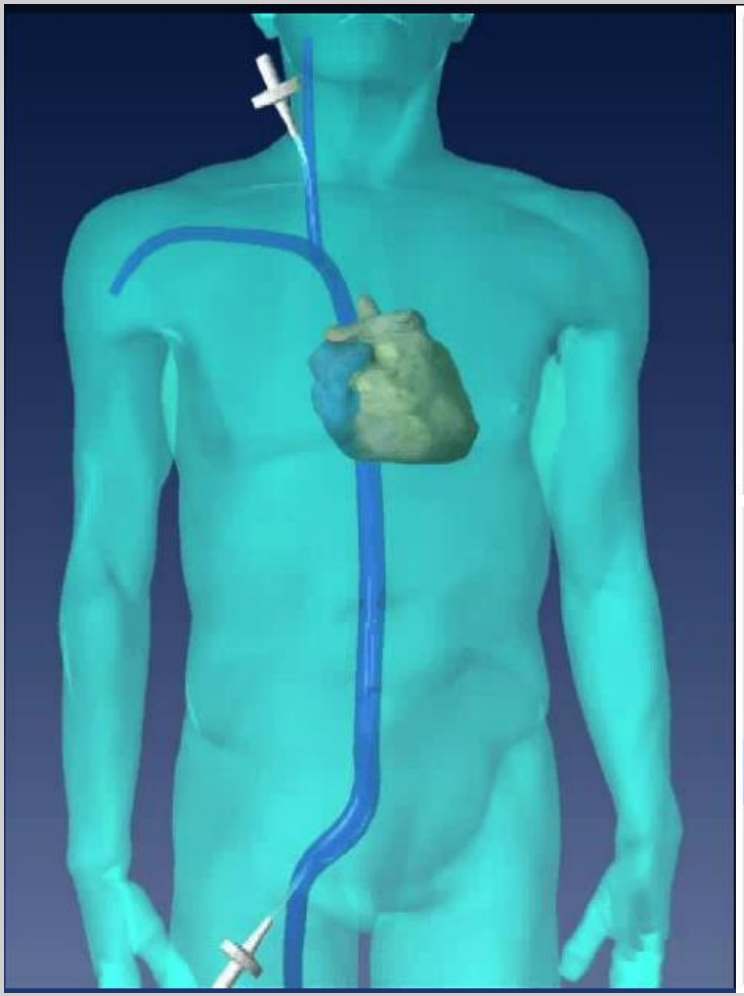
Acutely **reversible or removable**

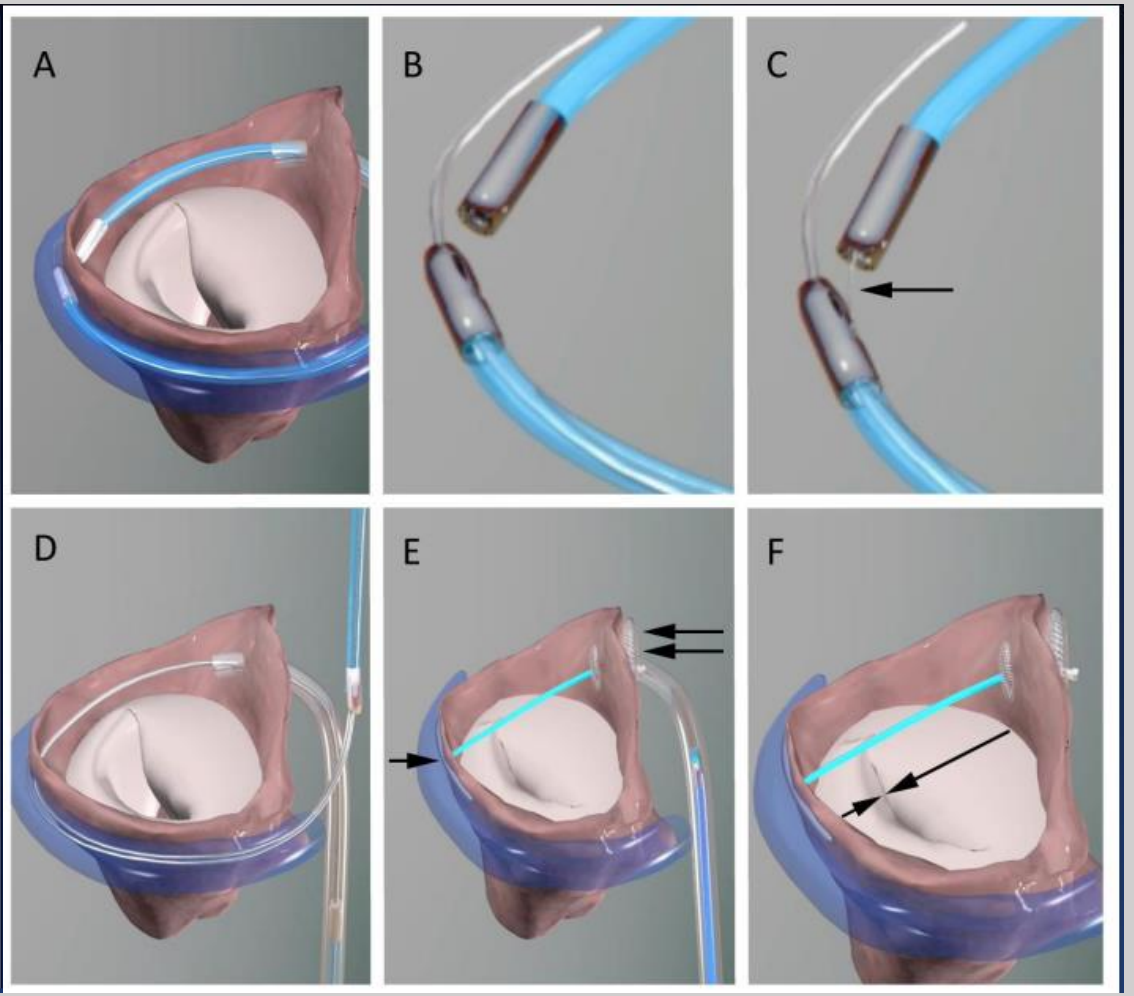
12 Fr Delivery System

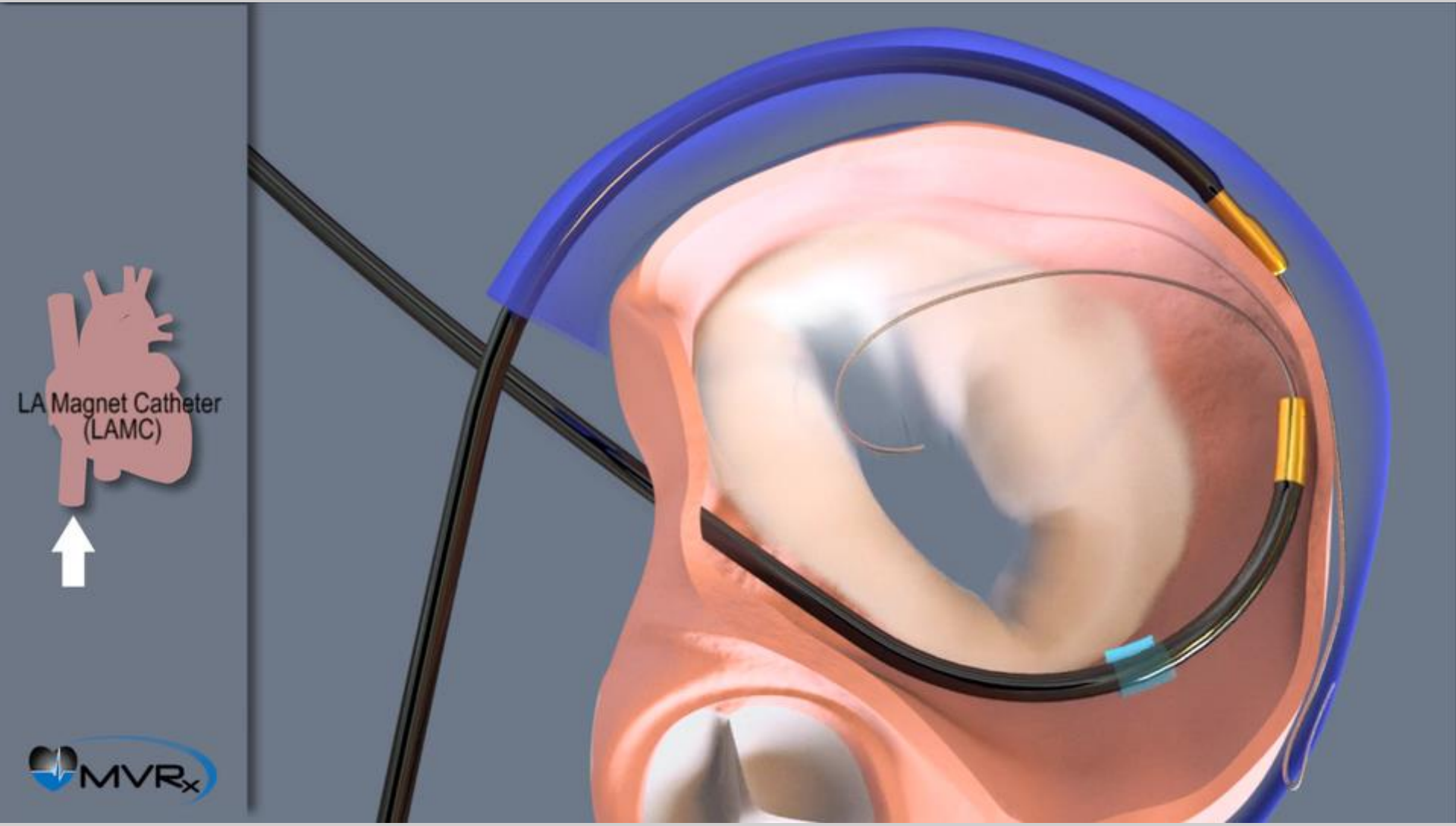
No residual ASD, no trauma to native mitral valve leaflets or chords

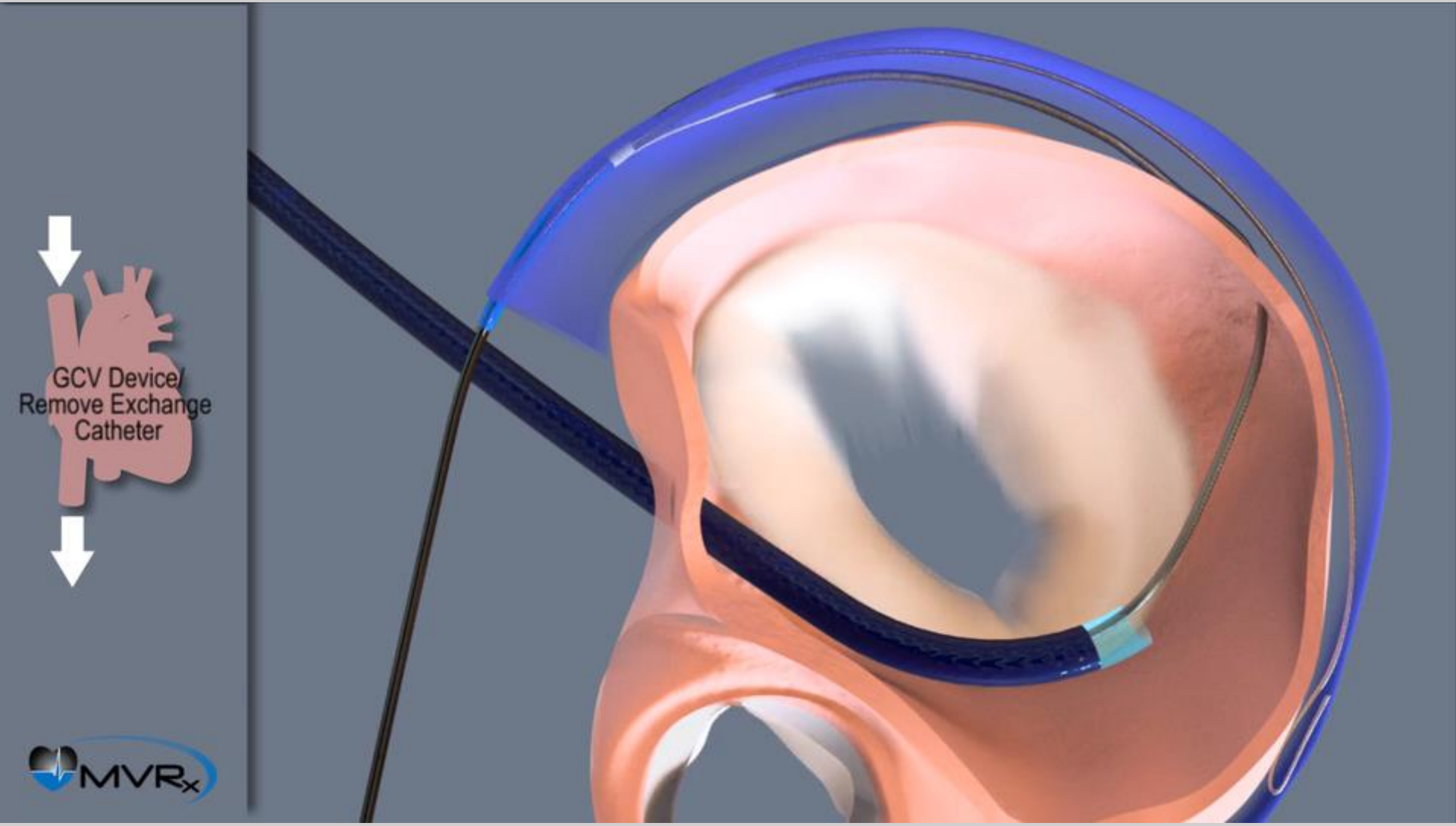


ARTO Deployment Procedure






LA Magnet Catheter
(LAMC)
MVRx



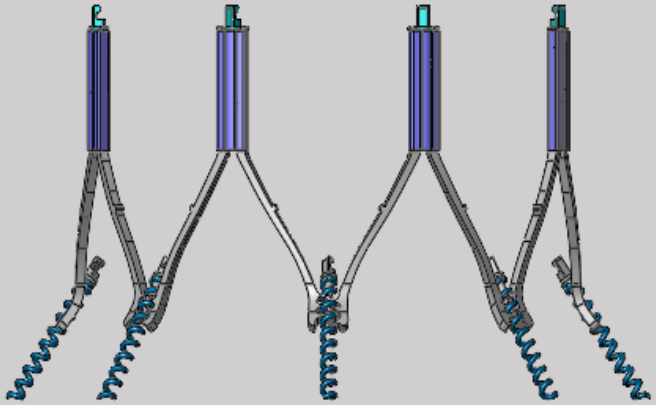
Arto System

Millipede IRIS [Boston Scientific]

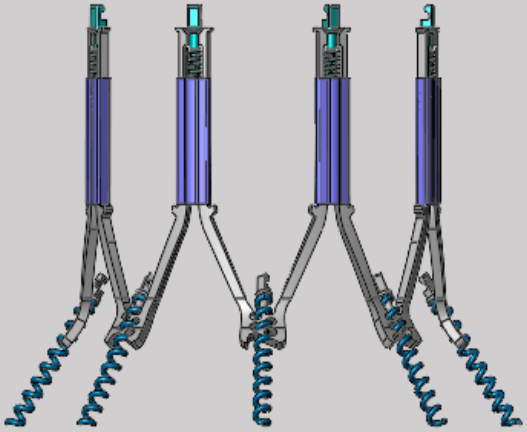
Millipede Transcatheter Annuloplasty System

- Replicates surgical repair with transseptal delivered annuloplasty
- Familiar TEE navigation with ICE-guided anchoring for a streamlined procedure
- Customizable, repositionable and retrievable
- Leaves options open for future interventions

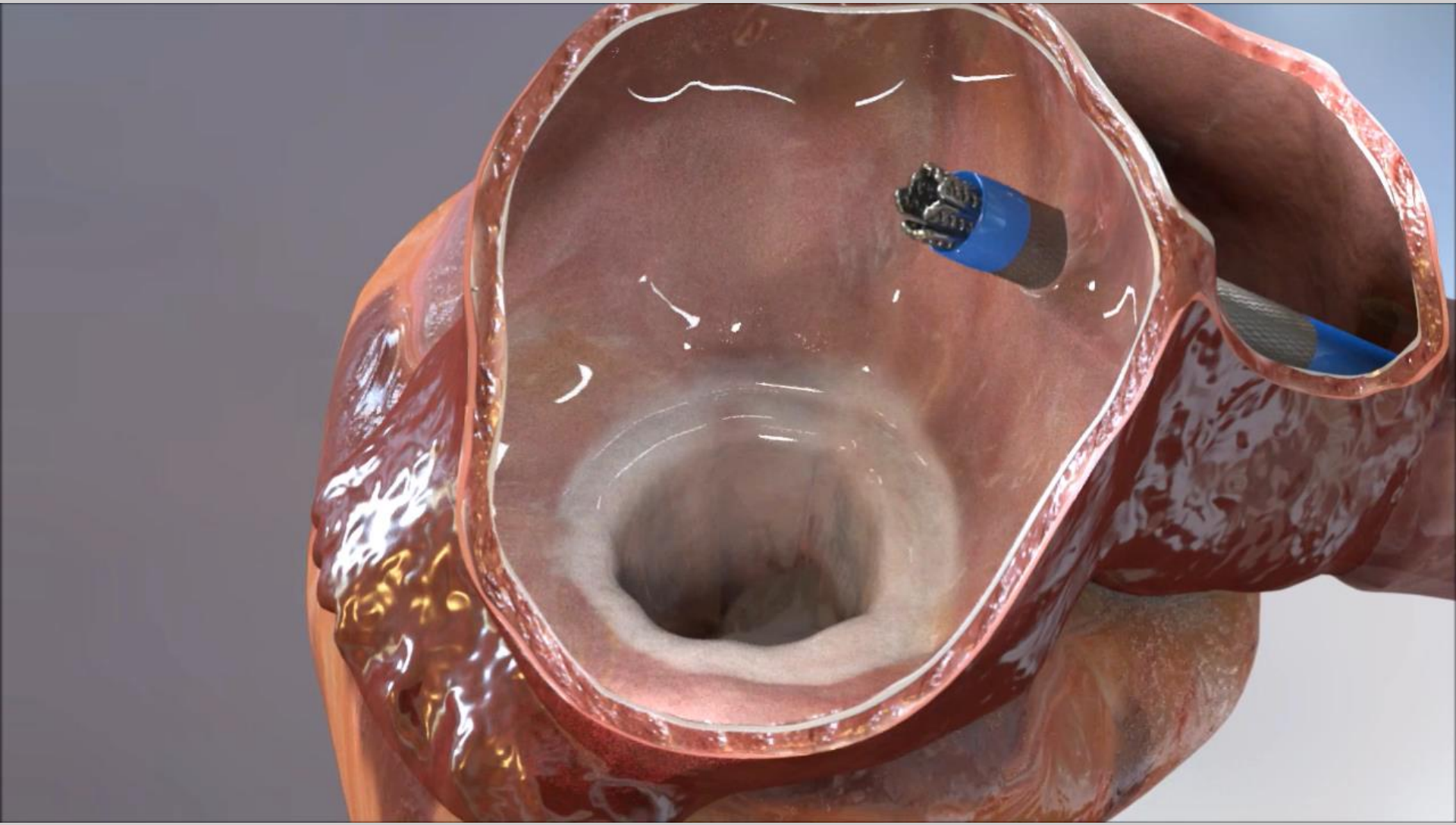
Placement



Anchor



Actuate

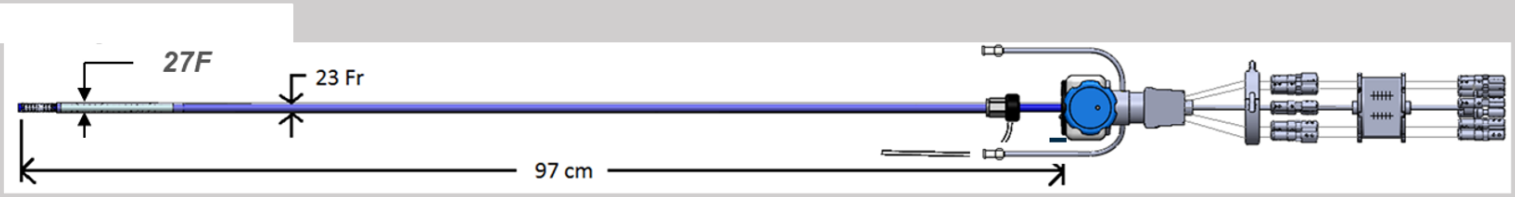


Millipede Transcatheter Annuloplasty Ring System with Integrated ICE Imaging

Millipede Transcatheter Annuloplasty System

Guide Catheter

Delivery Catheter



ICE Catheter

Familiar steering to land device

Adjustment knobs control anchoring and actuation

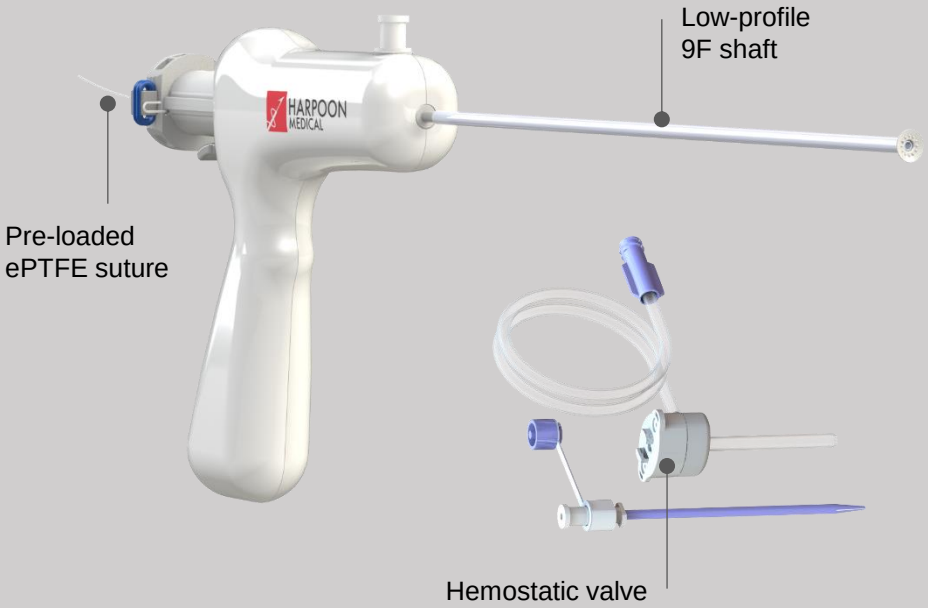
Standard imaging:
- Fluoro to access left atrium
- TEE to land device
- ICE to locate anchors

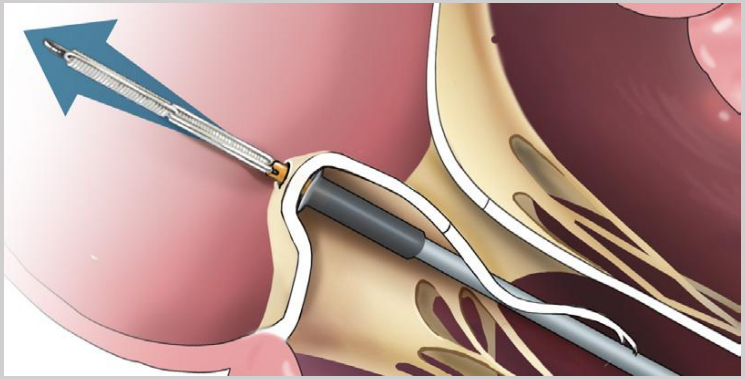
Others Mitral Repair Devices

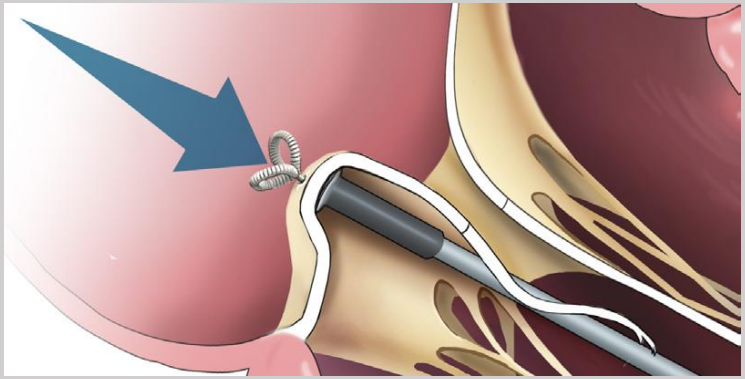
- Harpoon

HARPOON Beating-Heart Mitral Valve Repair System

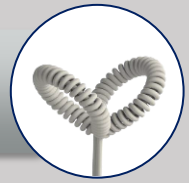
Delivery System and Introducer







Self-tying, double-helix knot on ePTFE suture



- Mitralign

14 Fr system

Delivery of pledgets

Achieve annuloplasty effect and MR reduction via plication

- Carillon

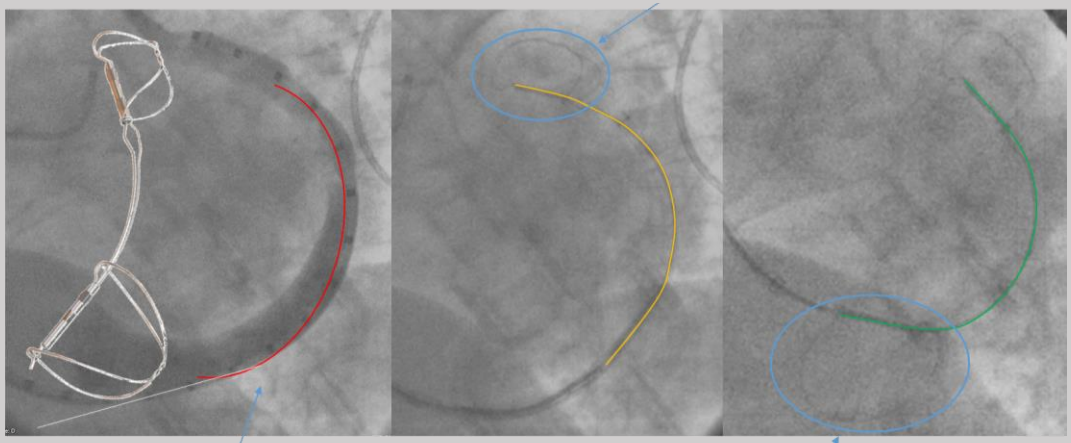
The Carillon Mitral Contour System – Indirect (Coronary Sinus) Annuloplasty Device

Distal Anchor
(in great cardiac vein)

Proximal Anchor
(in coronary sinus)

Anchor sizes are individually selected for each patient

Trans-jugular Delivery System

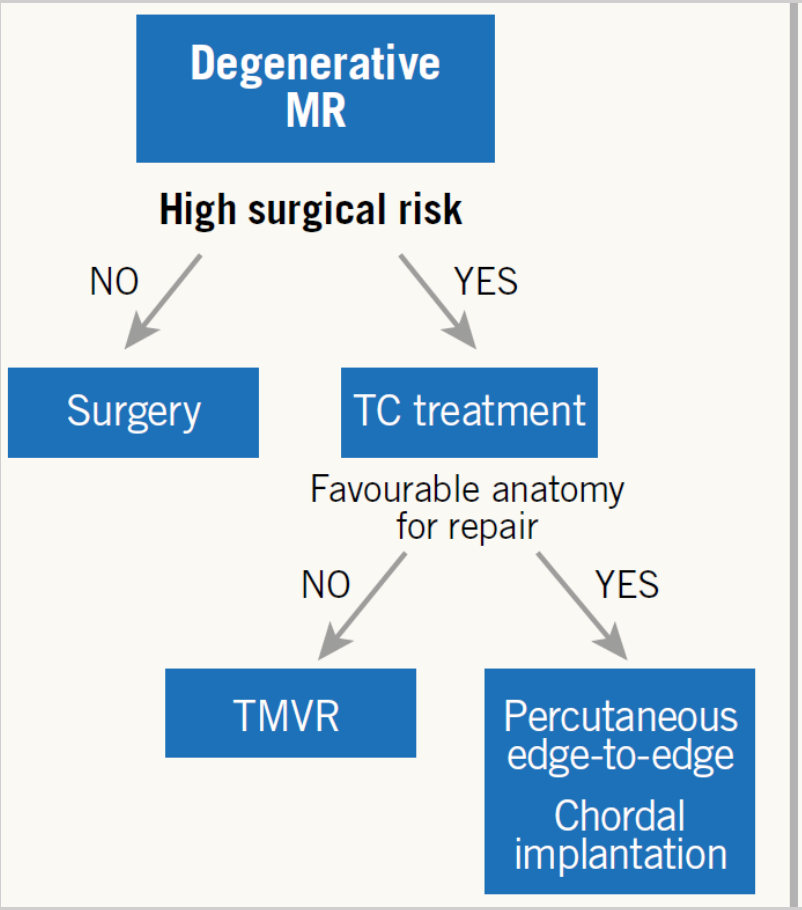


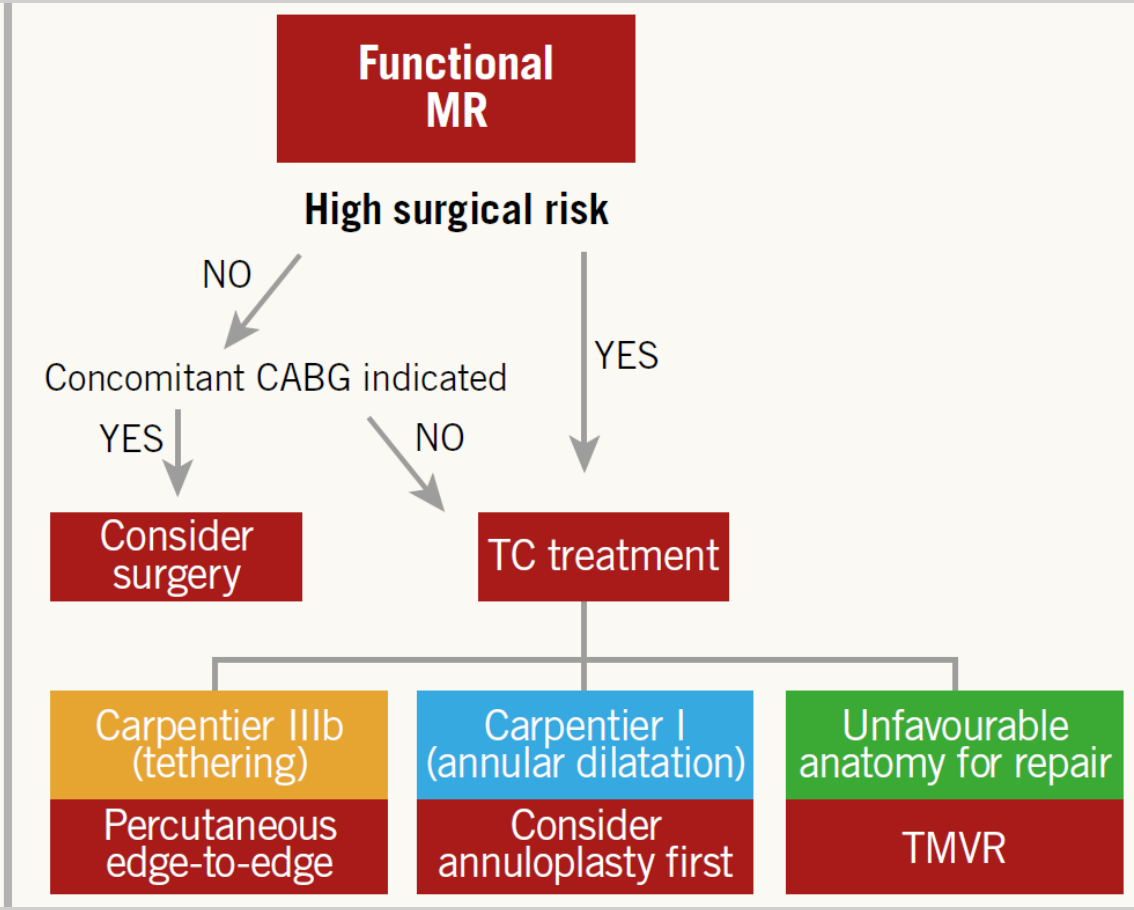
Coronary Sinus Angiogram to Define the Landing Zone

Tension Applied & Proximal Anchor Deployed

How to select the correct tool?

Algorithm for TMVRepair Strategy Selection





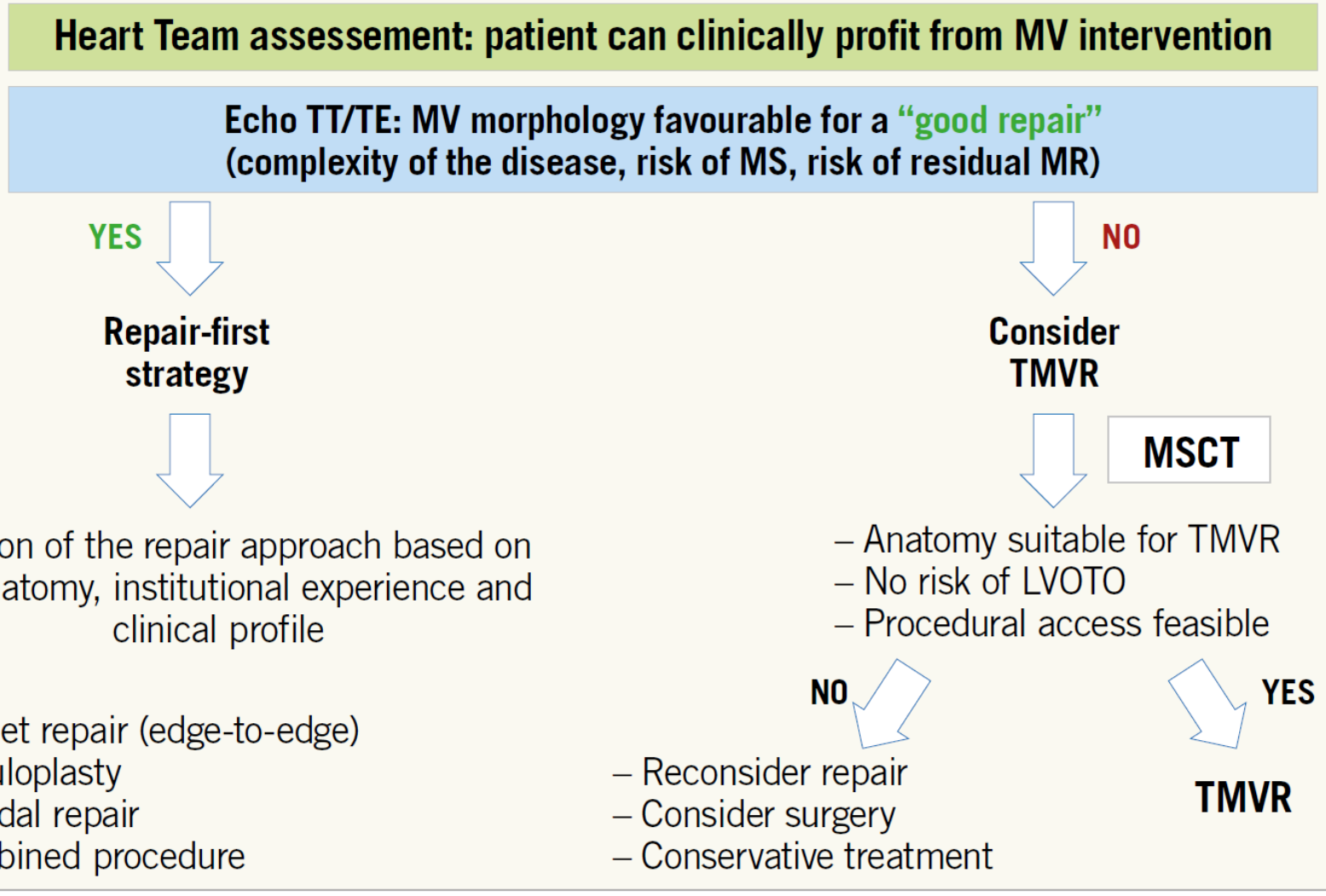
Taramasso M, Gavazzoni M, Nickenig G, Maisano F. Transcatheter mitral repair and replacement: which procedure for which patient? EuroIntervention 2019;15:867-874

Potential Factors/Anatomical considerations

TMVReplace vs Repair

Primary MR	Secondary MR
Thin, short, fragile, calcified leaflets Post-endocarditis (perforation, loss of tissue) Multi-segment complex Barlow Presence of significant MAC (selected cases) High risk of mitral stenosis: – rheumatic disease – combined MR/MS – valve doming – basal gradient >4 mmHg – baseline MVA <3 cm^2 Predicted residual relevant MR after repair: – complex multiple jets – wide flail width (complete eversion of flail in LA) – wide leaflet gap	Thin, short, fragile, calcified leaflets Severe annular dilatation* Severely restricted and shortened posterior leaflet Predicted residual relevant 2+ MR after repair: – complex multiple jets – MR across all the coaptation line

Heart Team Evaluation



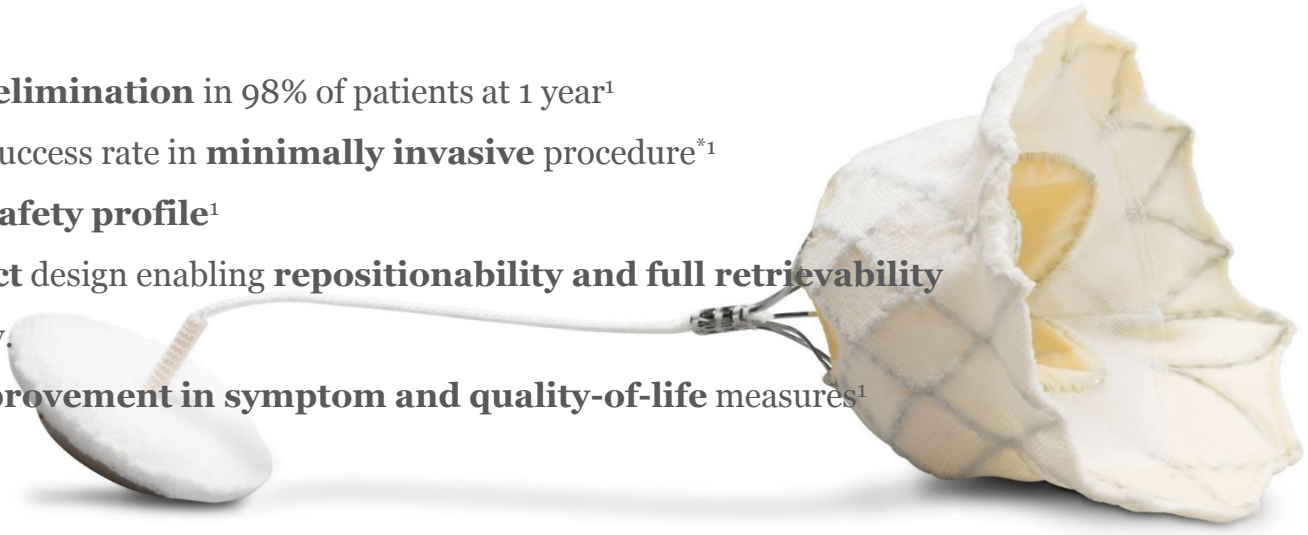
TENDYNE™

Transcatheter Mitral Valve Implantation

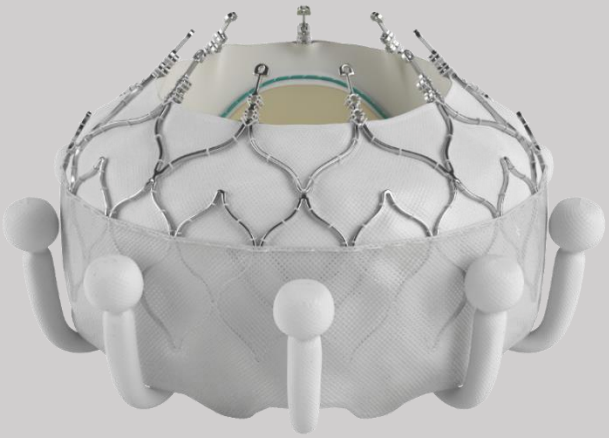
ABBOTT'S TENDYNE™ DEVICE RECEIVES WORLD'S FIRST CE MARK FOR TRANSCATHETER MITRAL VALVE IMPLANTATION

- First-of-its-kind technology addresses critical need to eliminate mitral regurgitation when surgery or mitral repair is not an option
- Tendyne valve provides relief from heart failure symptoms and quality-of-life improvement in high-surgical-risk patients
- Together with MitraClip™, Tendyne expands Abbott's market-leading portfolio of innovative minimally invasive mitral valve solutions

- Sustained **MR elimination** in 98% of patients at 1 year[1]
- 96% technical success rate in **minimally invasive** procedure*[1]
- **Exceptional safety profile**[1]
- Unique **product** design enabling **repositionability and full retrievability** intraoperatively.
- Significant **improvement in symptom and quality-of-life** measures[1]

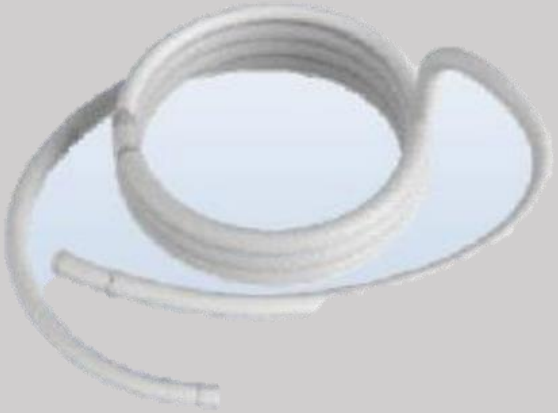


EVOQUE [Edwards Lifesciences]



M3

[Edwards Lifesciences]



Intrepid [Medtronic]

Conclusion

- Evolving technologies for TMVRepair
- More sophisticated and taking a longer path compared with aortic valve therapies
- Preserving valve structures with repair is still the goal, and more desirable if one technique opens future options for Hybrid/COMBO repair
- Understanding the limitations of TMVRepair
- TMVR as emerging options
- Heart Team Evaluation

HKU Med

MARRIOTT

Hong Kong Ocean Park Marriott Hotel

180 Wong Chuk Hang Road, Aberdeen, Hong Kong Hong Kong

HKU Med LKS Faculty of Medicine The University of Hong Kong 香港大學李嘉誠醫學院

瑪麗醫院 Queen Mary Hospital

HONG KONG VALVE HEART TEAM CONFERENCE

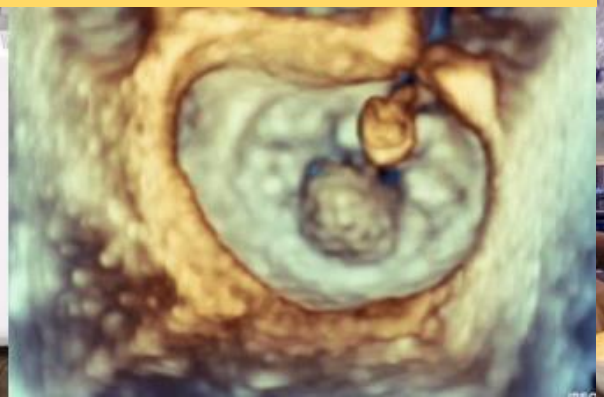
HONG KONG VALVE 2019

7-8TH SEPTEMBER 2019

Thank you!

See you on 17-18 Oct 2020!

HONG KONG VALVE
HEART TEAM CONFERENCE



Conference Secretariat
hkvalve@hku.hk
http://hkvalve.org