

Mitral Valve Repair With MitraClip : Complications

Ramon Quesada, MD, FACP, FACC, FSCAI

Medical Director, Structural Heart, Complex PCI & Cardiac Research
Miami Cardiac & Vascular Institute, Miami, Florida

Clinical Associate Professor of Medicine,
Florida International University
Herbert Wertheim School of Medicine



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

Disclosure Statement of Financial Interest

Affiliation/Financial Relationship

Company

Grant/Research Support

None

Consulting Fees/Honoraria

Abbott, Medtronic,
W.L. Gore,, Boston Scientific Corp.
Terumo

Major Stock Shareholder/Equity

None

Royalty Income

None

Ownership/Founder

None



Intellectual Property Rights

None

Other Financial Benefit

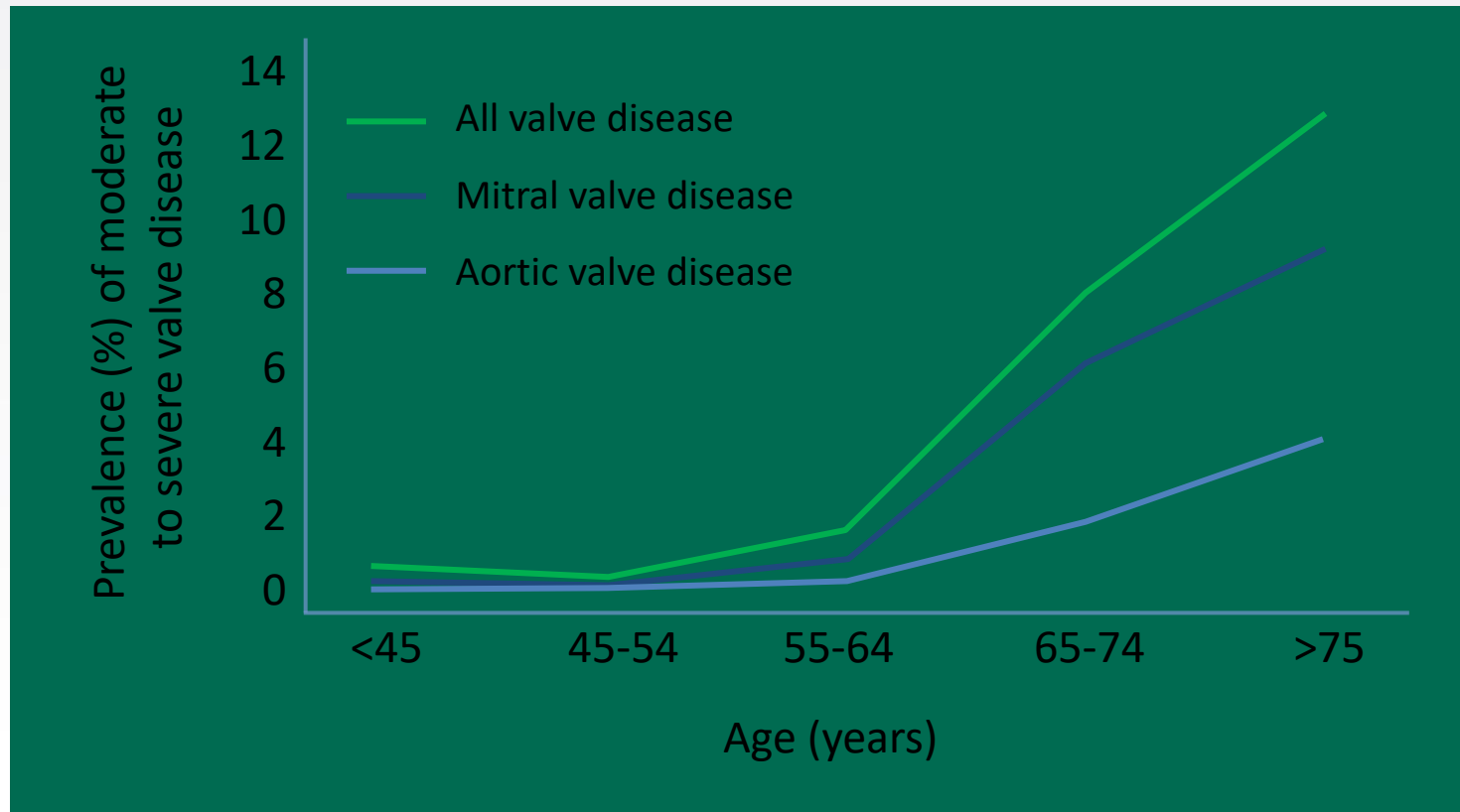
None

Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

Structural Heart Disease

Increases with Age



> 9.3% for ≥ 75 year olds ($p < .0001$)

Transcatheter Mitral Valve Repair

MitraCliptm



24 Fr, transseptal system for leaflet apposition and reduction in MR

>100,000 patients worldwide

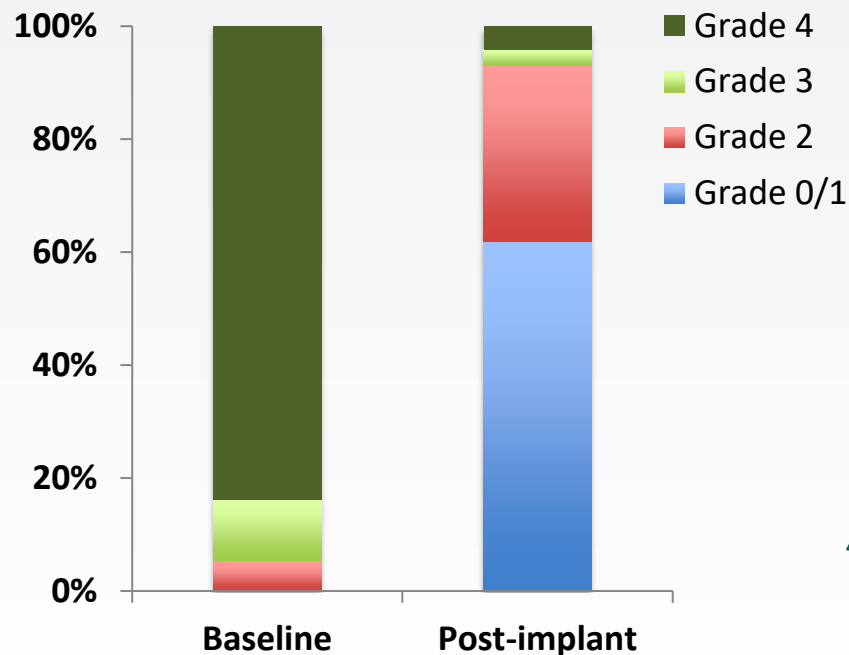
Approval in U.S. in October 2013
with 250 current sites



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

Acute Procedural Results STS/ACC TVT Registry



92.8% with post-procedural MR ≤2

SLDA, 1.5%

In-hospital mortality = 2.7%

85.9% discharged home

Median LOS, 2 days (1, 5 days)

Acute procedure success = 91.8%

Safety at 5 years: High Risk DMR Cohort

Key Measures of Device Safety

Key Measures of Device Safety	Through 1 Year	1 Year to 5 Years
Single Leaflet Device Attachment (SLDA)	0 (0.0%)	0 (0.0%)
MV stenosis	3 (2.4%)	1 (0.8%)
Device Embolization	0 (0.0%)	0 (0.0%)

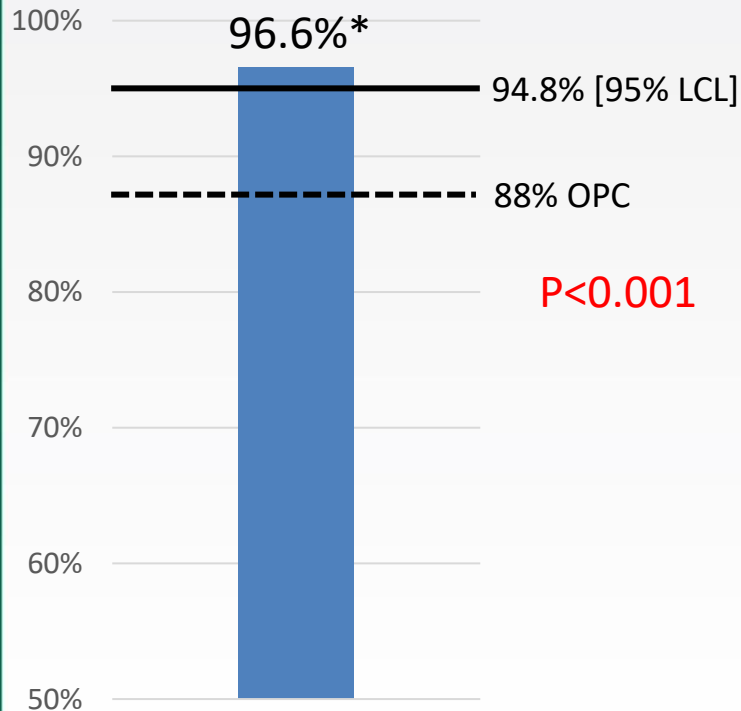
Re-Interventions

Re-Intervention	# (%) of patients	Time to Re-Intervention Post-Index Procedure
MV Surgery Post-Index Procedure	4 (3.2%)	2, 26, 56, and 1,100 days
Second Intervention to Place an Additional MitraClip	3 (2.4%)	2.1, 4.2, and 4.9 years



Primary Safety Endpoint

Freedom from Device-related Complications within 12 months



MitraClip procedure attempted	N=293
Device-related complications	9 (3.4%)
- Single leaflet device attachment	2 (0.7%)
- Device embolization	1 (0.3%)
- Endocarditis requiring surgery	0 (0.0%)
- Mitral stenosis requiring surgery	0 (0.0%)
- Left ventricular assist device implant	3 (1.2%)
- Heart transplant	2 (0.8%)
- Any device-related complication requiring non-elective CV surgery	1 (0.3%)

*KM estimate; **Calculated from Z test with Greenwood's method of estimated variance against a pre-specified objective performance goal of 88%

COAPT vs. MITRA-FR: MitraClip Outcomes

	COAPT (n=302)	MITRA-FR (n=152)
MitraClip attempted	293 (97.0%)	144 (94.7%)
≥1 Clip implanted	287 (95.0%)	138 (90.8%)
Procedural complications	25/293 (8.5%)	21/144 (14.6%)
- Device implant failure	6 (2.0%)	6 (4.2%)
- Transfusion or vasc compl requiring surgery	16 (5.5%)	5 (3.5%)
- ASD	2 (0.7%)	4 (2.8%)
- Cardiogenic shock	1 (0.3%)	4 (2.8%)
- Cardiac embolism/stroke	1 (0.3%)	2 (1.4%)
- Tamponade	1 (0.3%)	2 (1.5%)
- Urgent cardiac surgery	1 (0.3%)	0 (0%)
Acute result: MR ≥3+	5%	9%
12-month result: MR ≥3+	5%	17%

Stone GW et al. NEJM. 2018 Sept 23; Obadia JF et al. NEJM. 2018 Aug 27. doi: 10.1056/NEJMoa1805374



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

Acute Procedural Results

	High Risk DMR	STS/ACC TVT Registry	Post-Approval Study
Implant Rate	95.3 %	92.8 %	97.1 %
SLDA	0 %	1.5 %	1.6 %
30-day Mortality	6.3 %	2.7 %	5.0 %
Discharge Home	88 %	85.9 %	NR



Safety

	High Risk DMR	STS/ACC TVT Registry	Post-Approval Study
Device embolization	0.0 %	0.1 %	0.2 %
SLDA	0.0 %	1.5 %	1.6 %
Other device-related	0.02 %	0.7 %	0.8 %
Stroke	2.4 %	0.4 %	0.8 %
Mitral reintervention	0.01 %	0.7 %	0.6 %

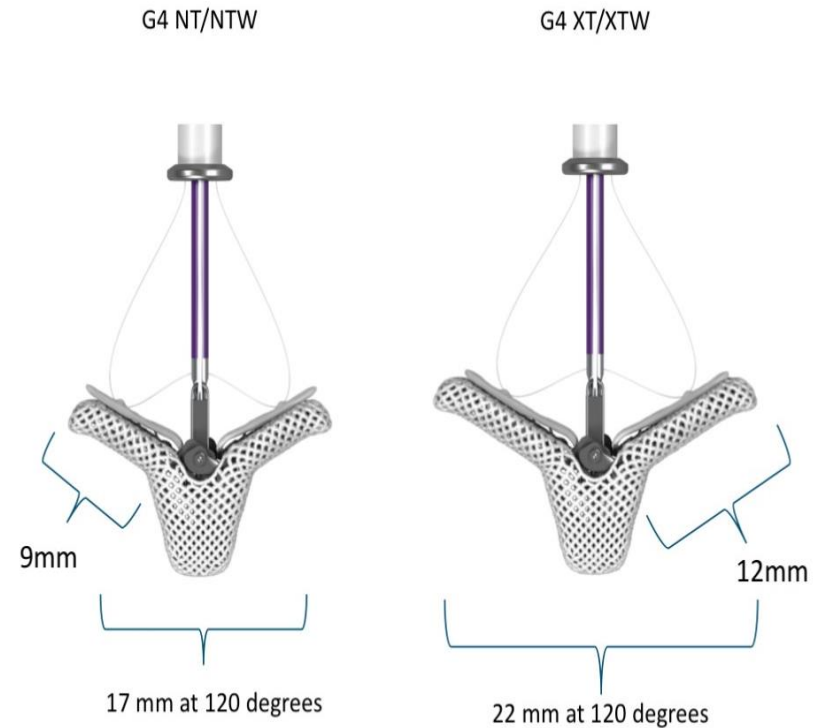
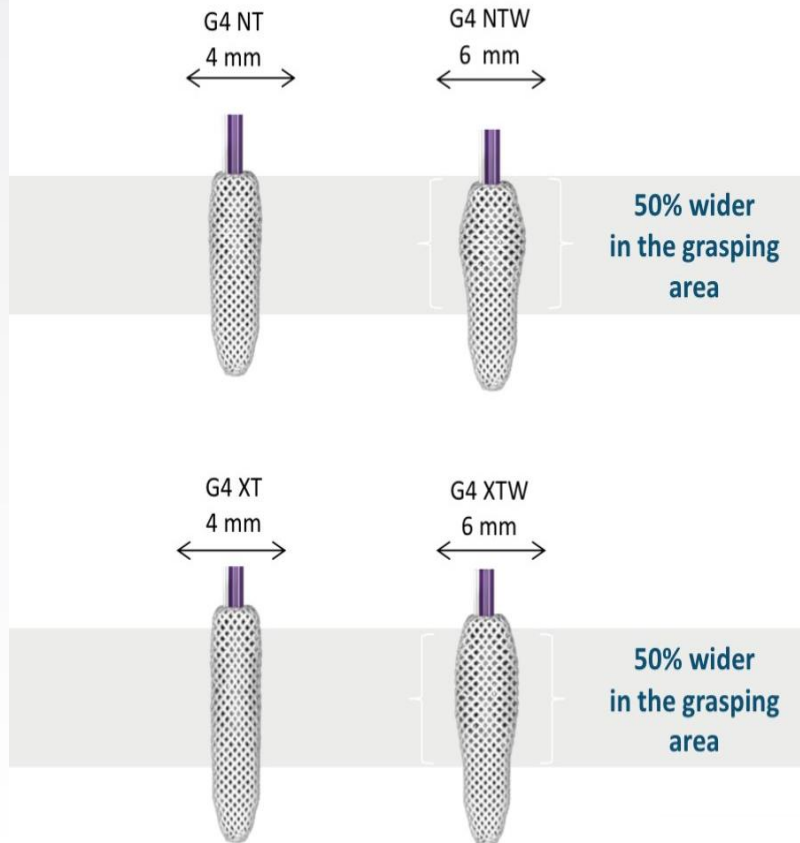


A Scoring Proposal

Complexity	Anatomy
Simple (Level 1)	P2 prolapse, P2 Prolapse with RCT A2/P2 Prolapse
Complex (Level 2)	Cleft P2 –Multi segment Prolapse
Complex (Level 3)	Commissural Prolapse Annular Calcium Barlow syndrome
Super Complex (Level 4)	Barlow with extremely dilated annulus Leaflet calcification Multi-segment prolapse with clefts Post MV repair, Dynamic MR



MitraClip™ G4: Expanded Clip Size to Tailor MV Repair



RECOMMENDATION: NTR-XTR CLIP SIZE SELECTION CONSIDERATIONS

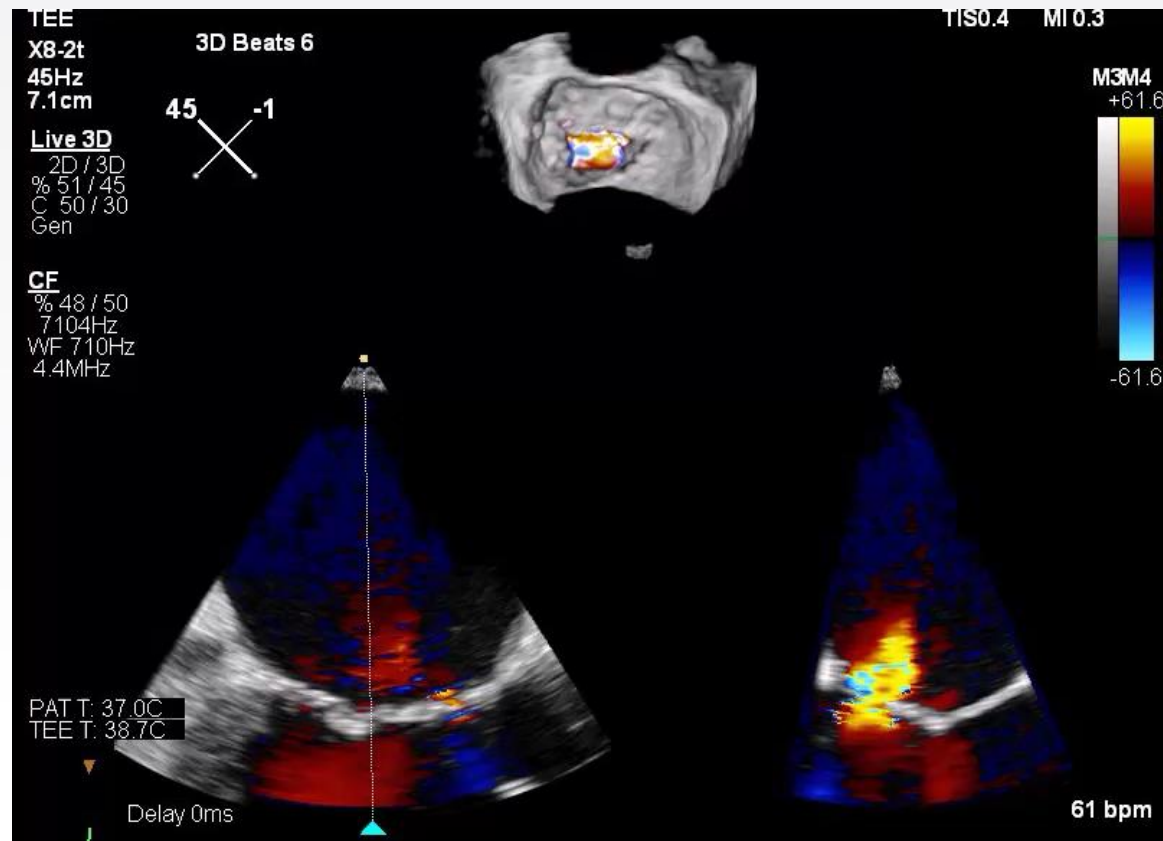
Anatomical Considerations		Favored XTR	Favored NTR
Leaflet insertion	Longer leaflet ¹	+	
	A2-P2	+	
	Large flail ²	+	
	Redundant leaflet	+	
	Restricted leaflet ³		+
Tissue quality	Calcification of annulus and leaflet ⁴		+
Gradient	Smaller MV area ⁵		+
Cordial entrapment	Mitral valve commissures ⁶		+

Footnotes:

1. NTRclip arm length is maximum 9 mm with ≥ 6 mm of leaflet insertion needed for complete frictional element engagement. XTR clip arm length is maximum 12 mm with ≥ 9 mm of leaflet insertion needed for complete frictional element engagement.
2. IFU states flail width <15 mm and flail gap <10mm
3. IFU includes treatment of severely restricted posterior leaflet as a warning
4. IFU includes severe calcification in the grasping area and/or annulus as a warning
5. IFU states Mitral valve area ≥ 4.0 cm²
6. IFU includes treatment of a primary jet outside of the A2-P2 as a warning



TEE 11/04/2019: Severe MR



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

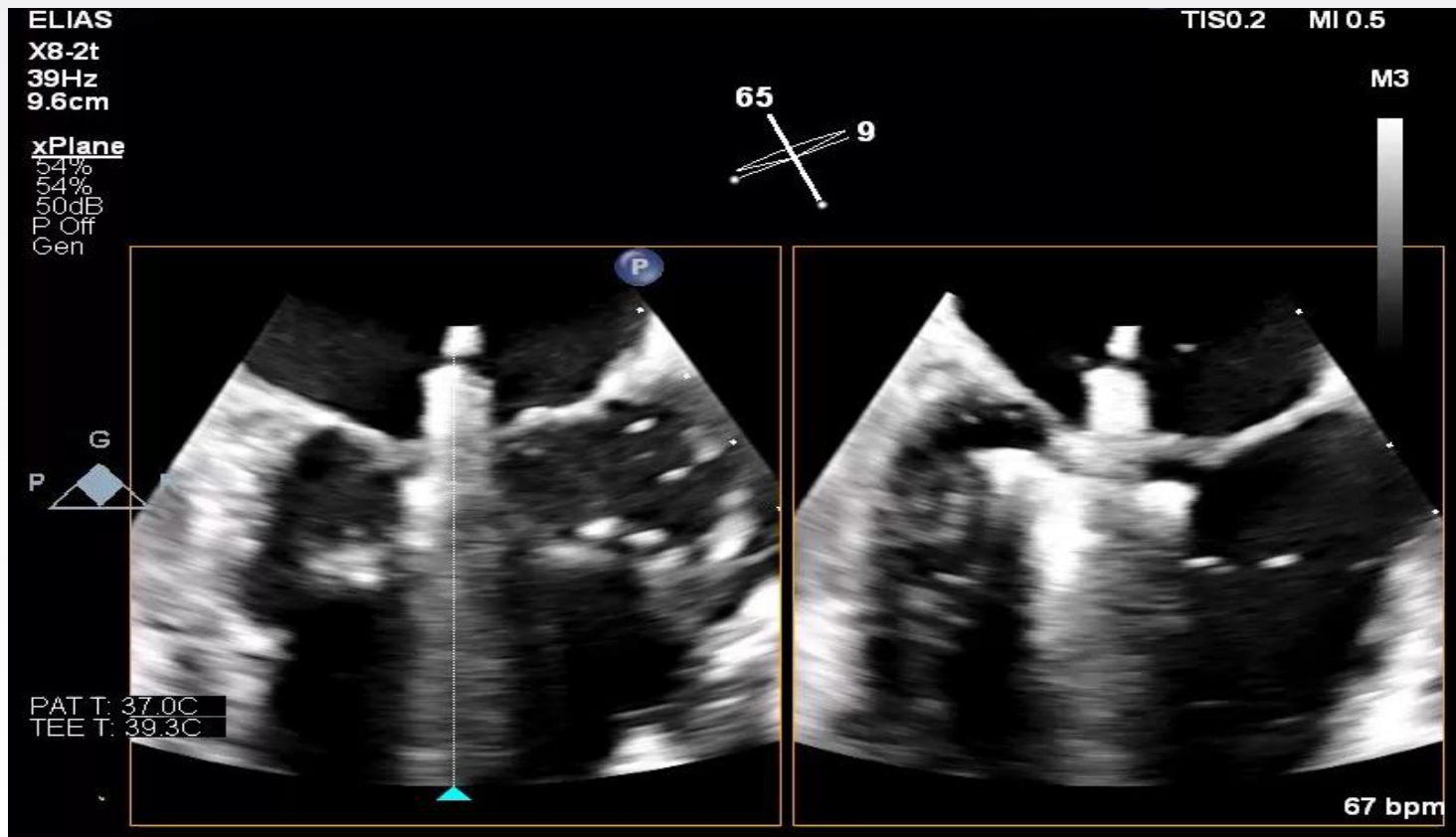
XTR Perpendicular to Coaptation



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

XTR Grasping



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

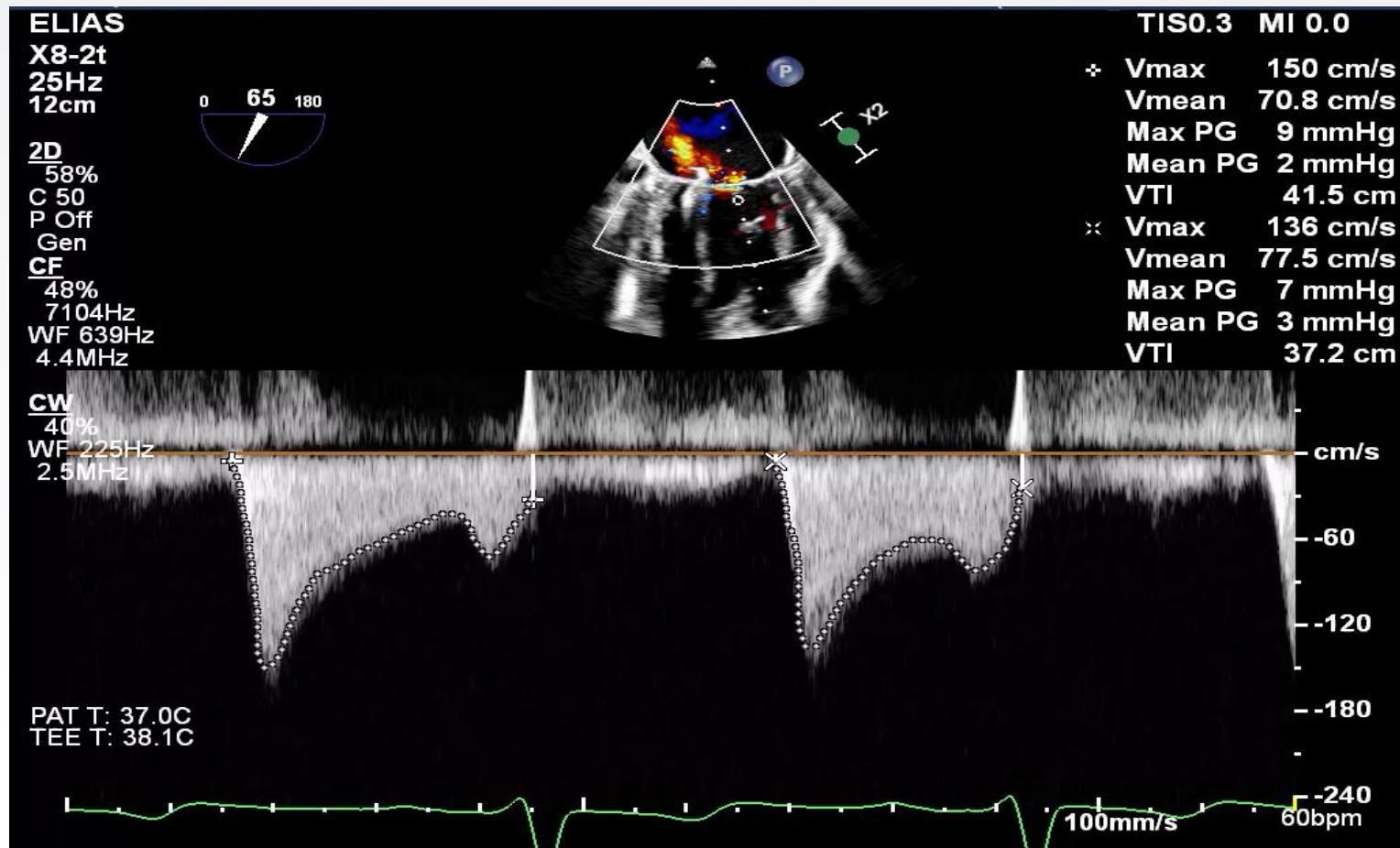
3D Assessing Grasp



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

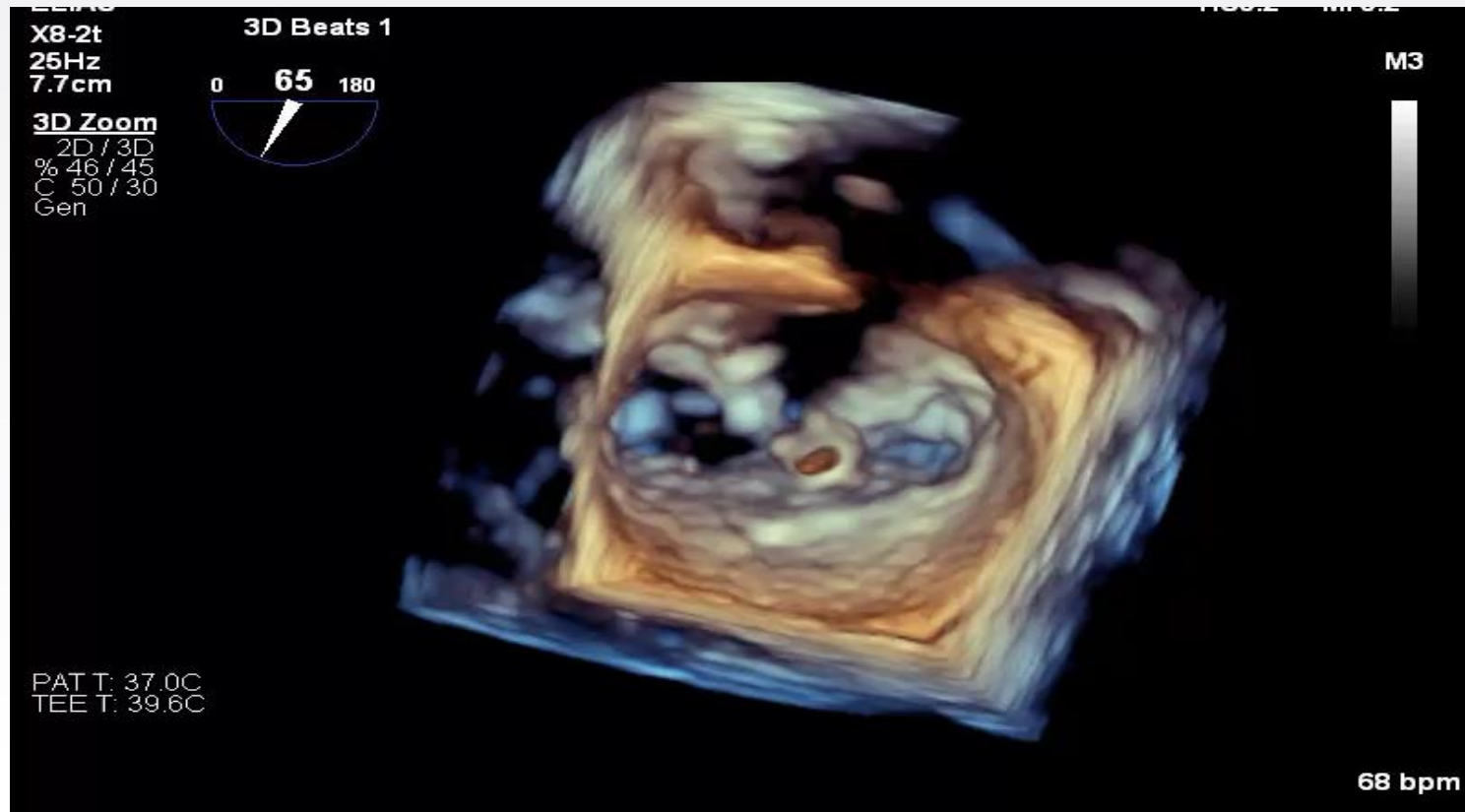
Gradients Pre Release: 2 mmHg



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

Final Grasp Assessment



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

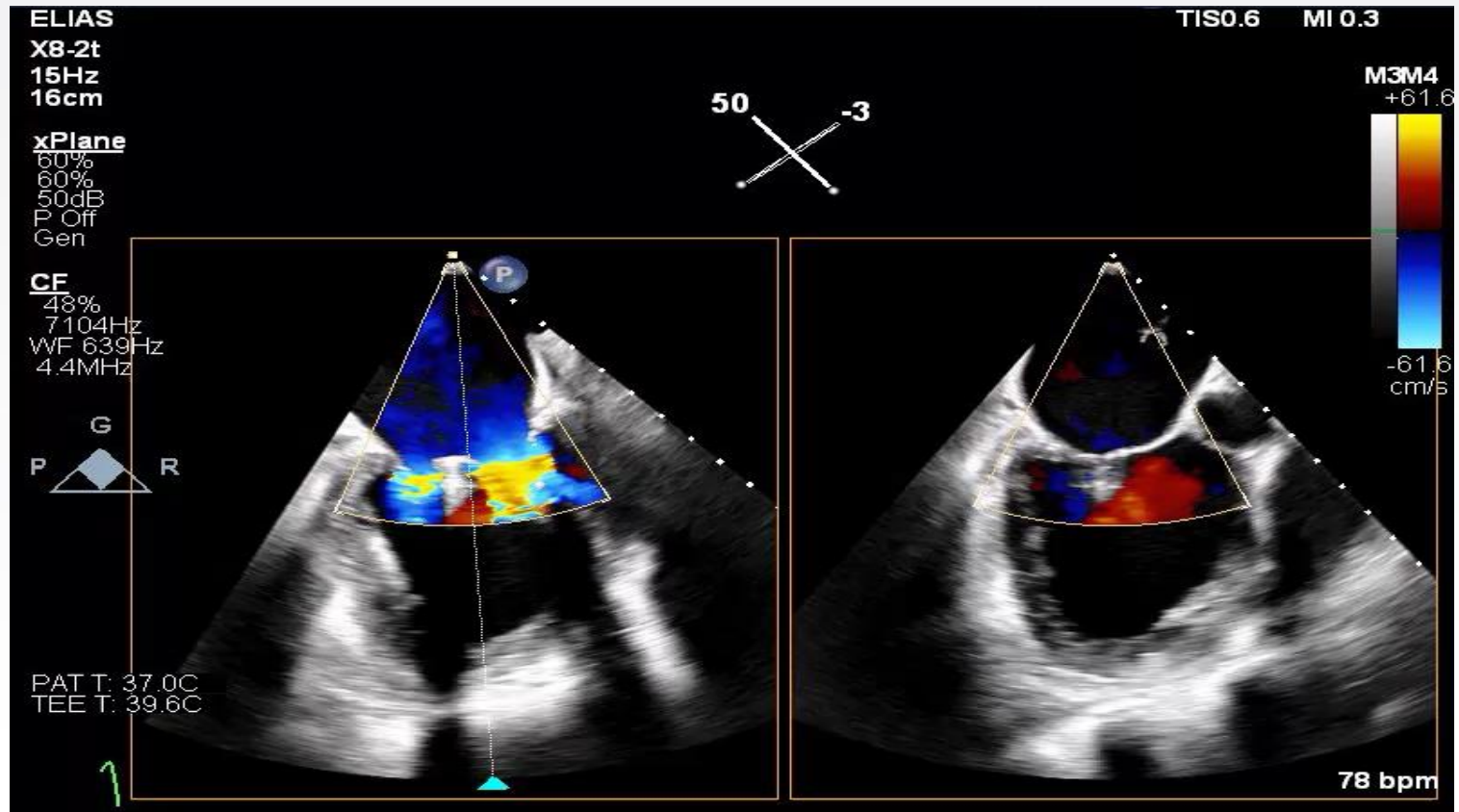
XTR MitraClip : Release



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

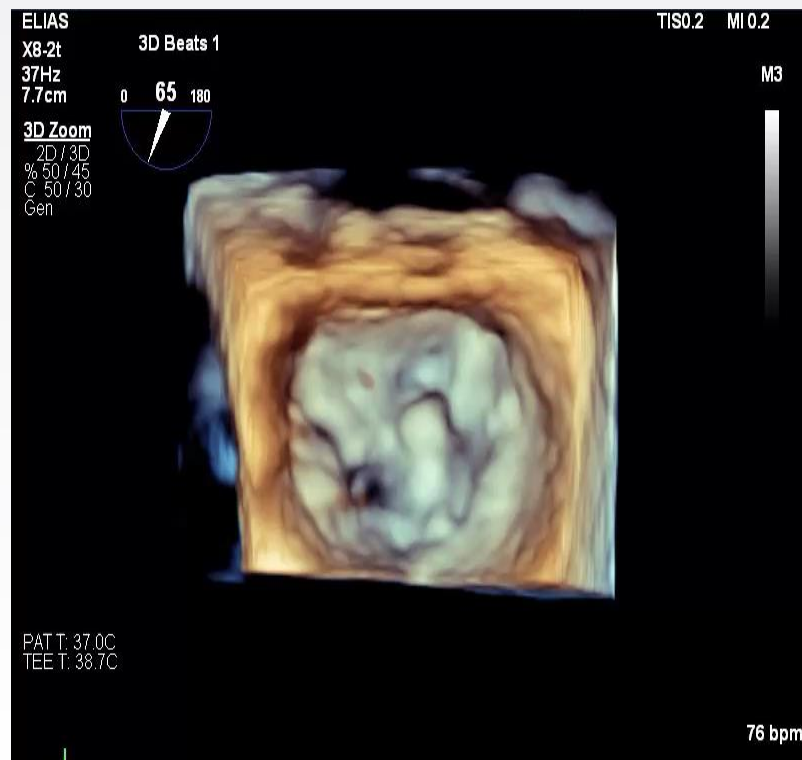
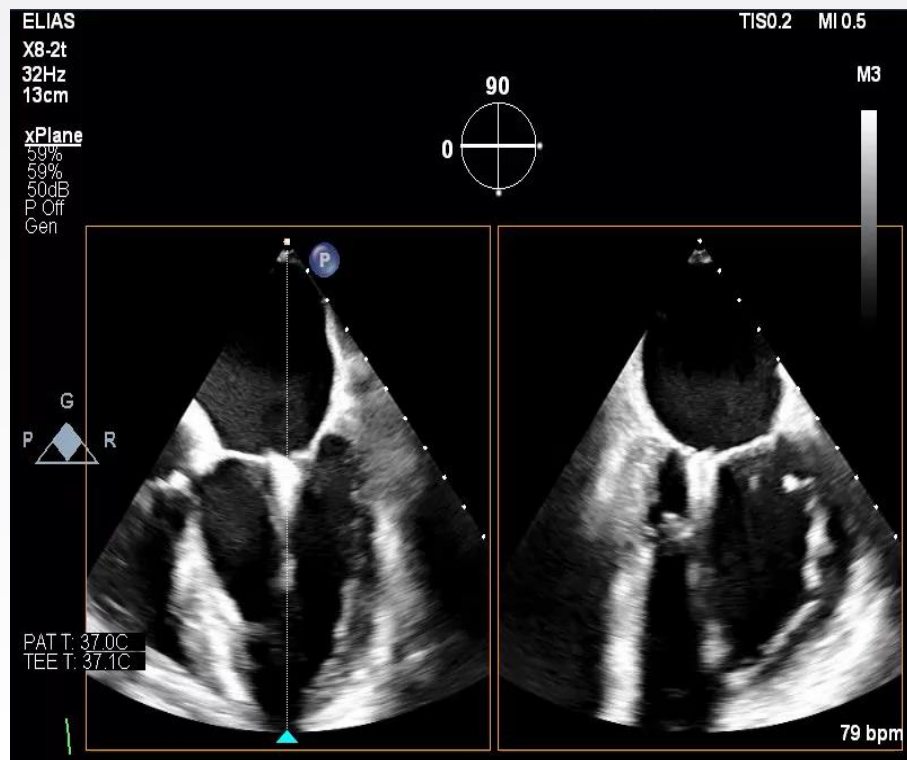
Final Results 11/4/2019



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

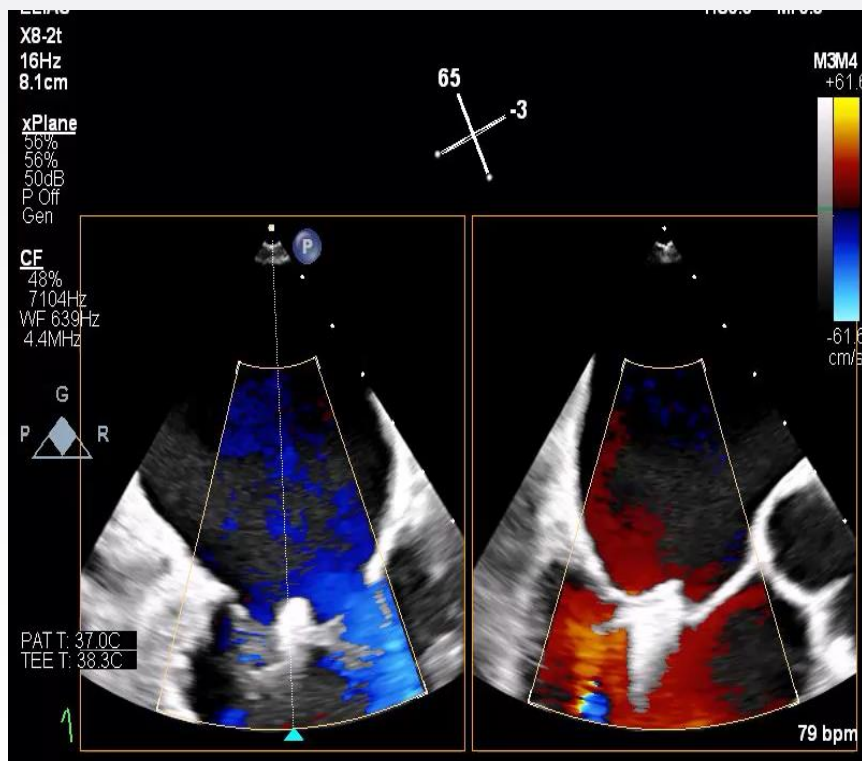
TEE 11/6/2019 : Oh No what Happen !!!!



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

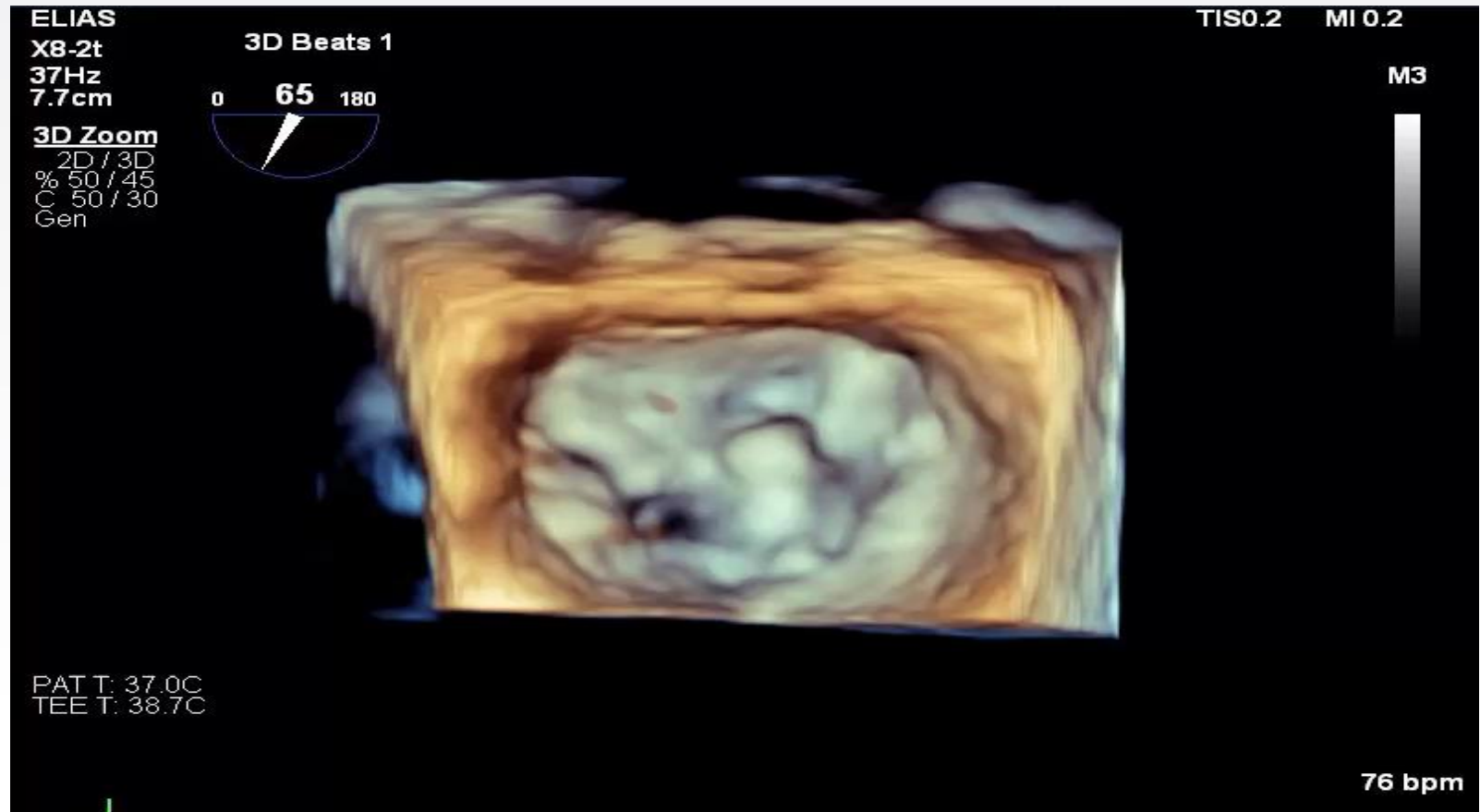
Worsening MR, patient back in CHF



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

Single Leaflet Device Attachment (SLDA)

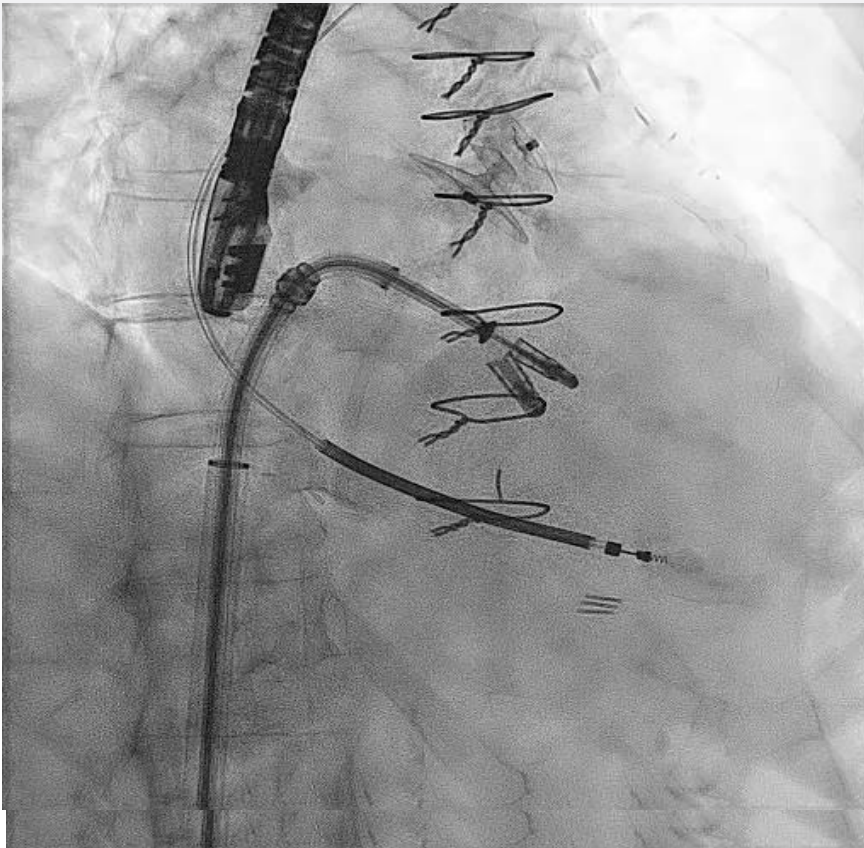


Miami Cardiac & Vascular Institute

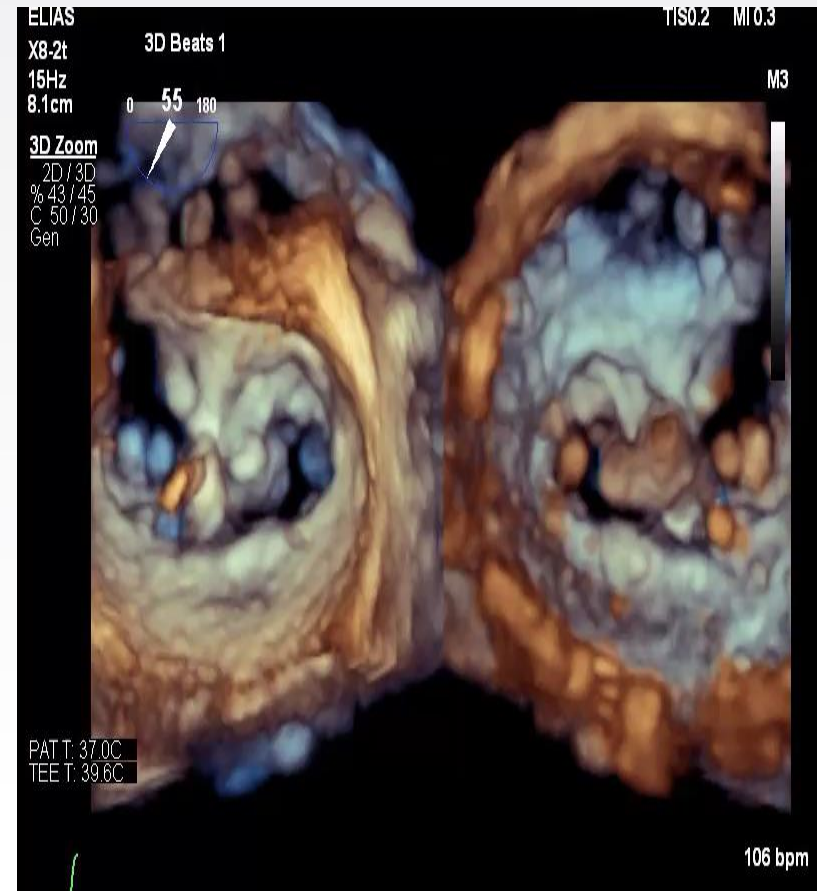
BAPTIST HEALTH SOUTH FLORIDA

SLDA Place a second Clip next to it

Asses Clip Position/Interaction



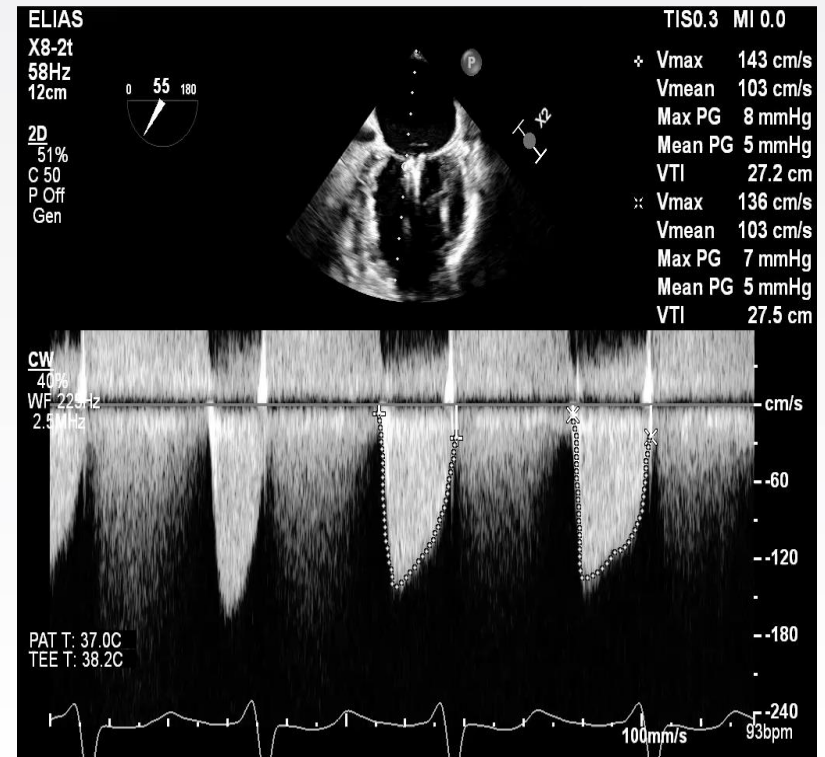
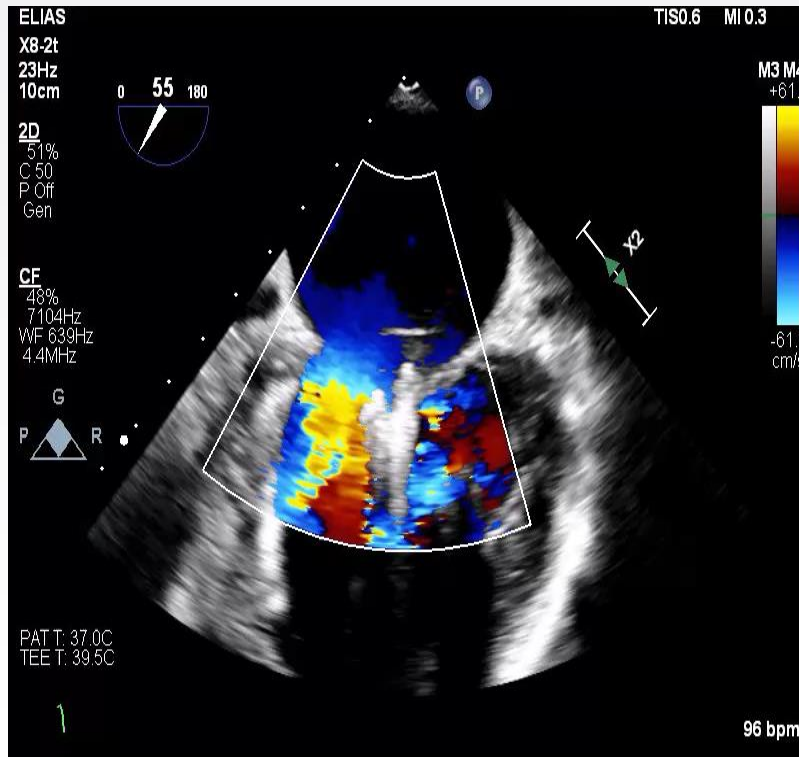
Asses Grasp Stability



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

SLDA Repair: Results and 5mmHg gradient



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

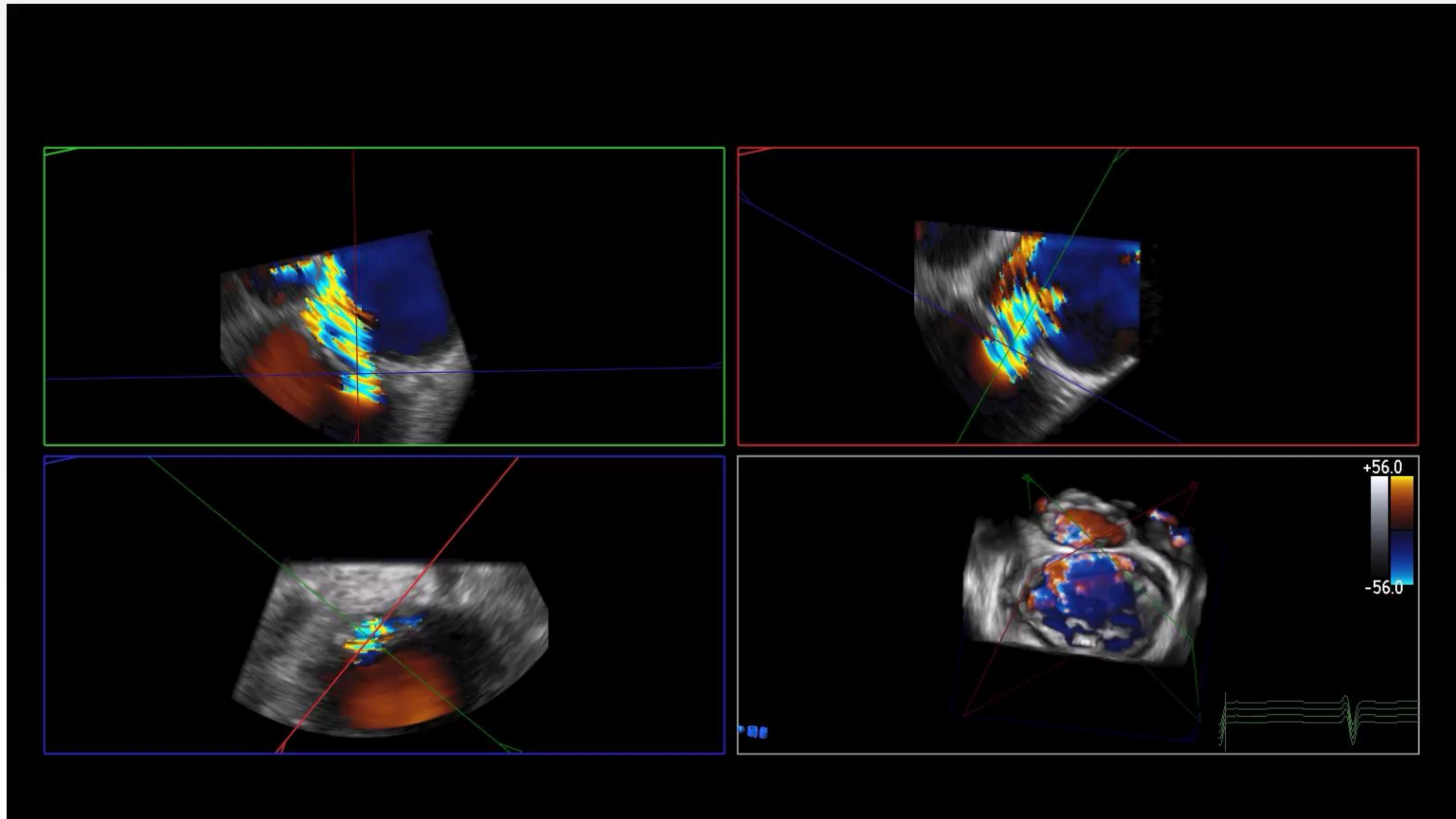
SLDA Repair : Final Results



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

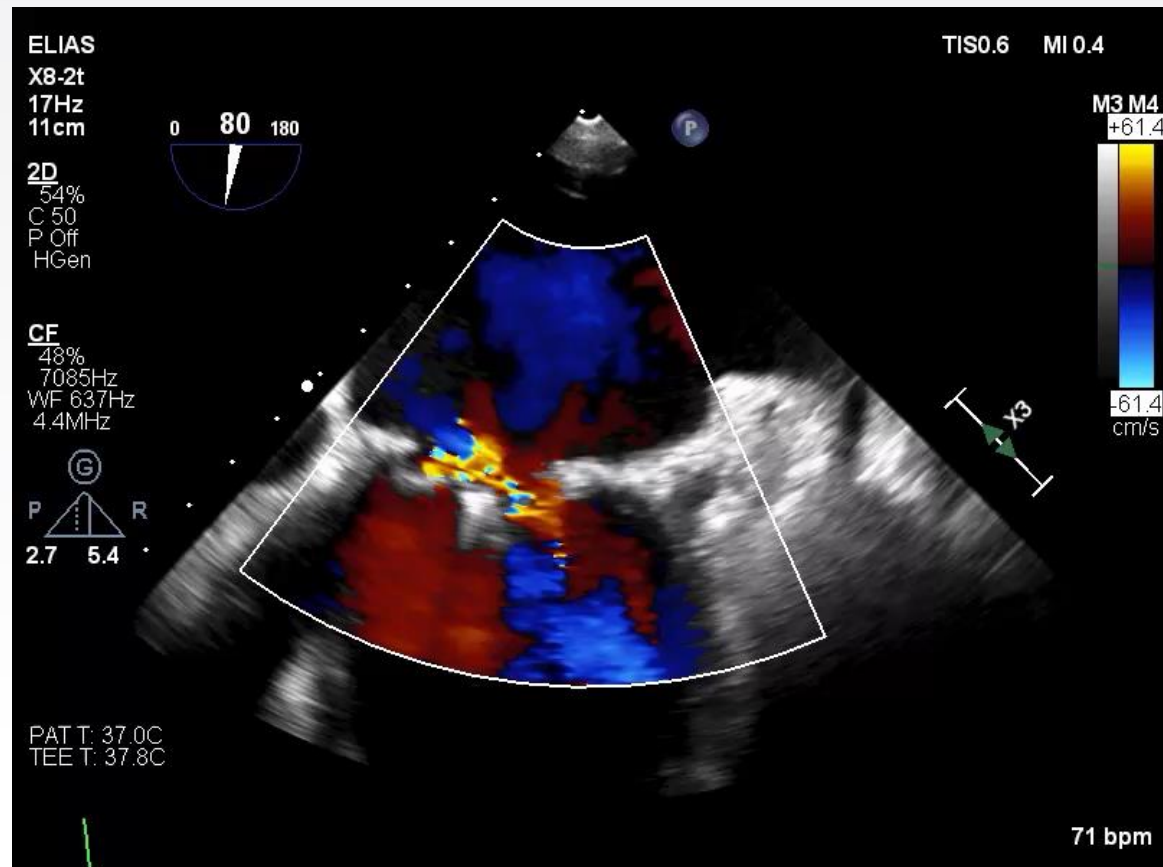
85 y/o M, severe MR and TR, Class III



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

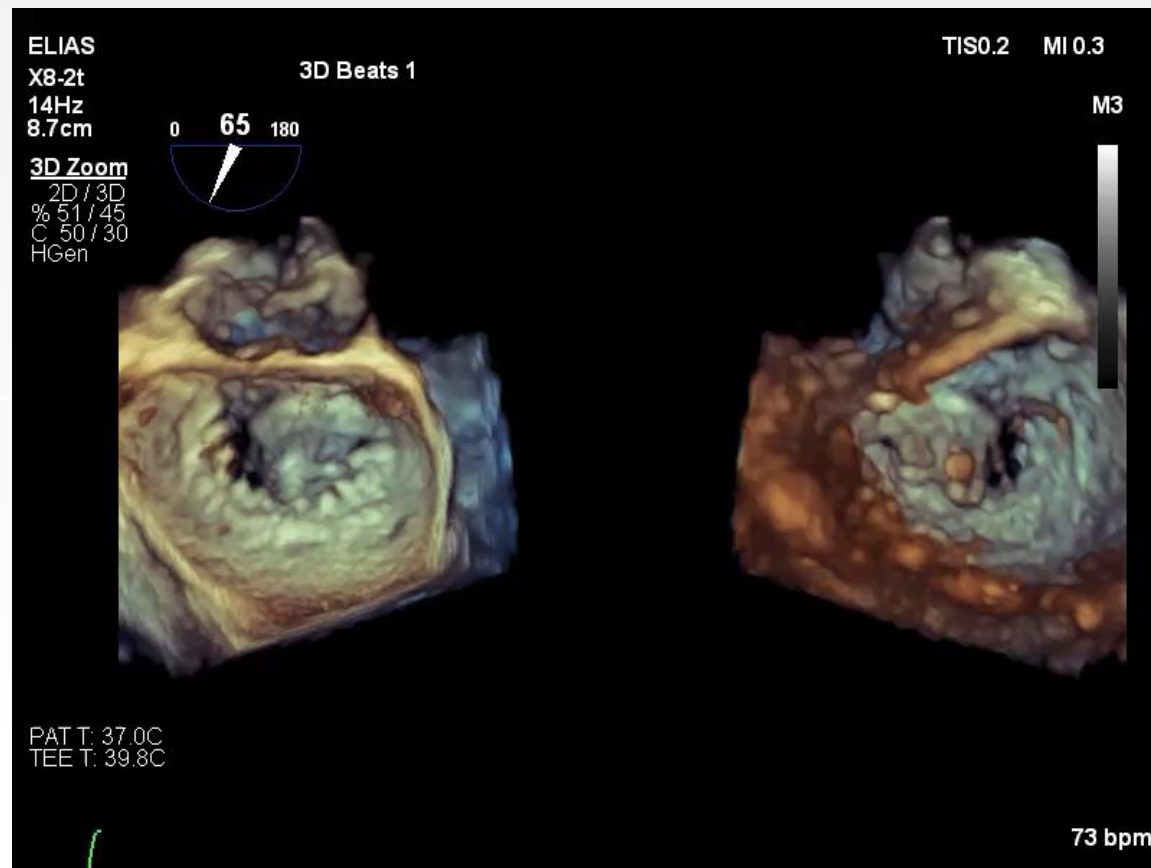
MVr Two MitraClips XTR + NTR



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

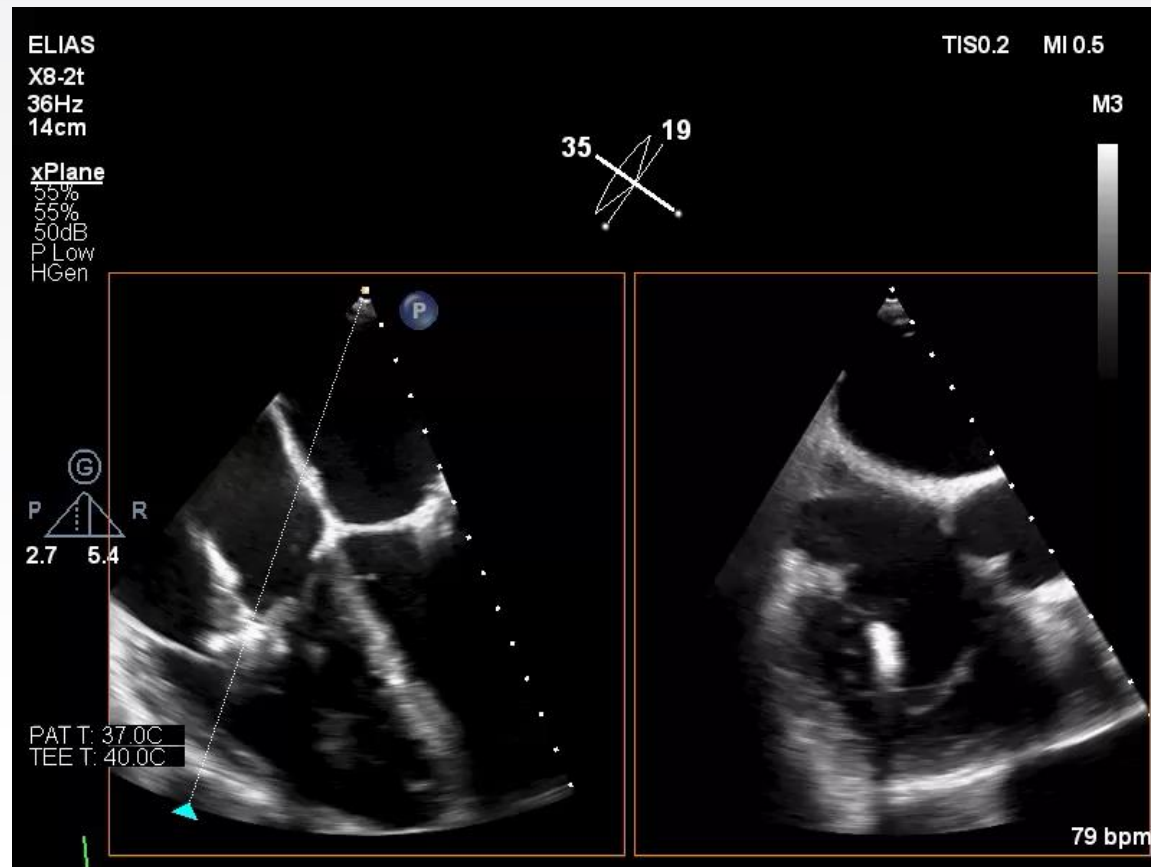
Post MitraClip repair 3D



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

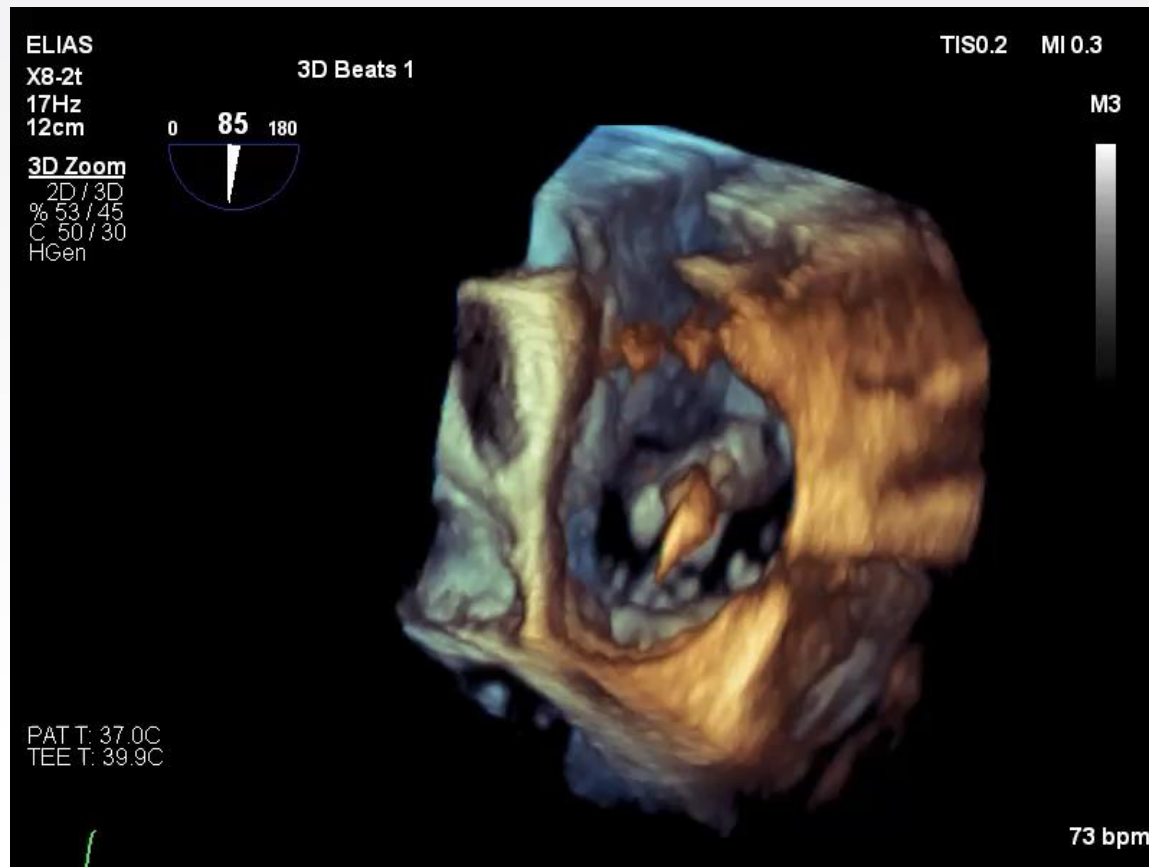
Tricuspid Valve Repair with MitraClip



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

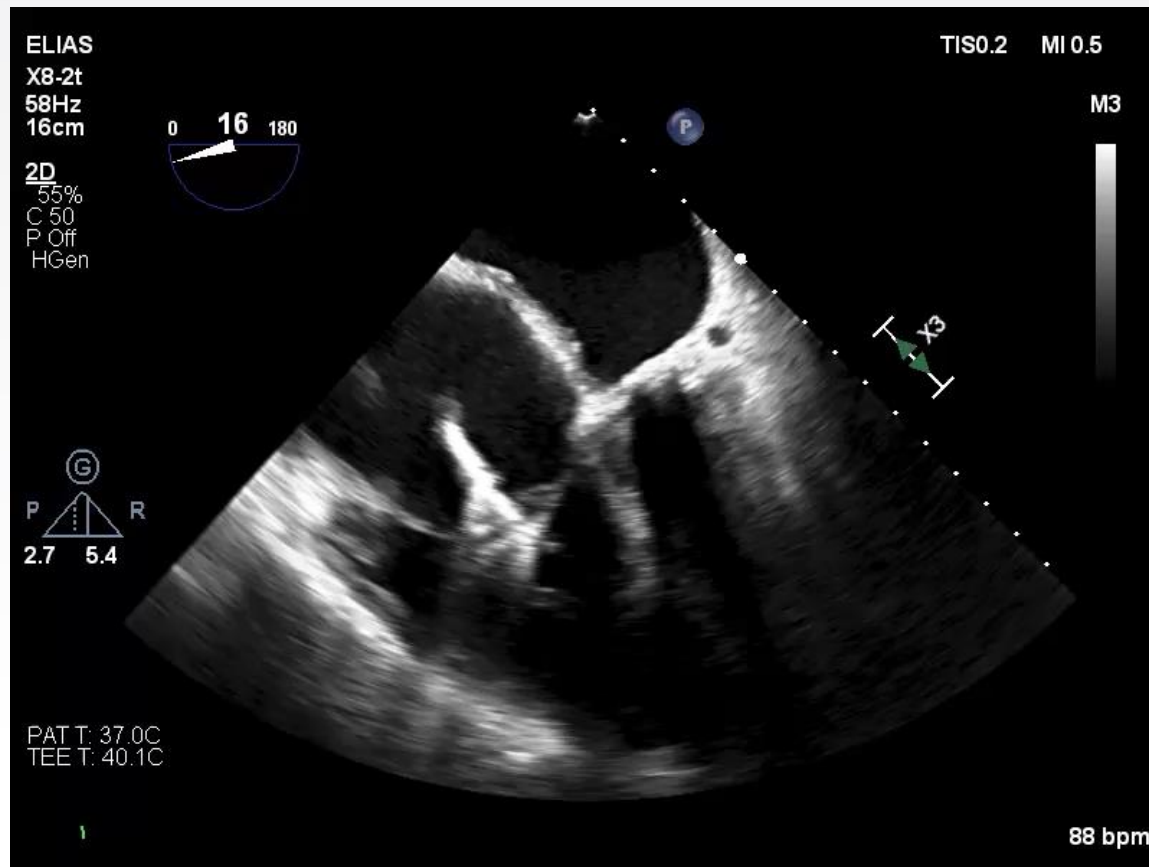
TV Clip positioning Perpendicular



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

Tricuspid MitraClip Grasping attempts.



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

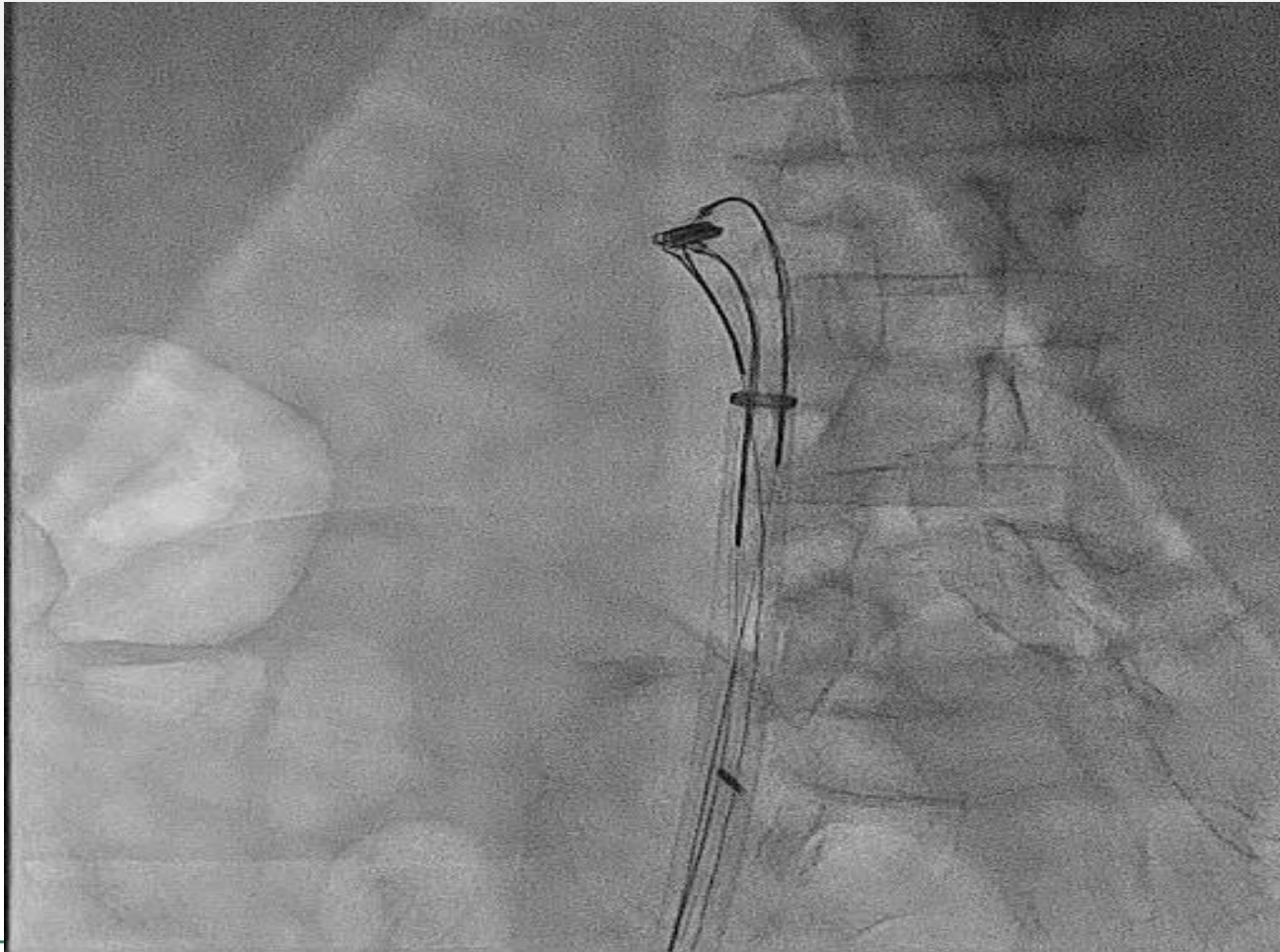
Clip Embolization, rare but can Happen



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

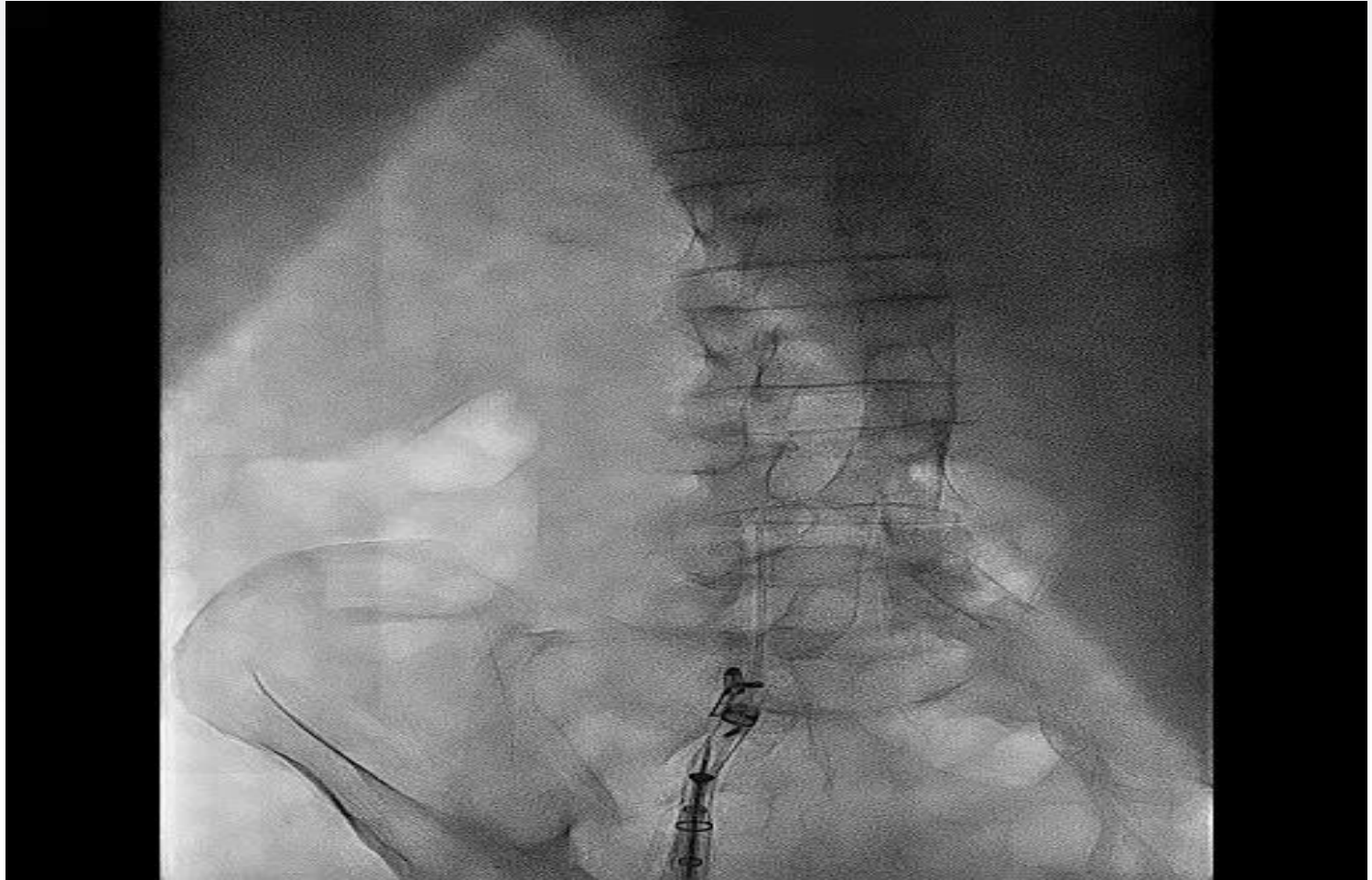
Grasping one arm of the Clip



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

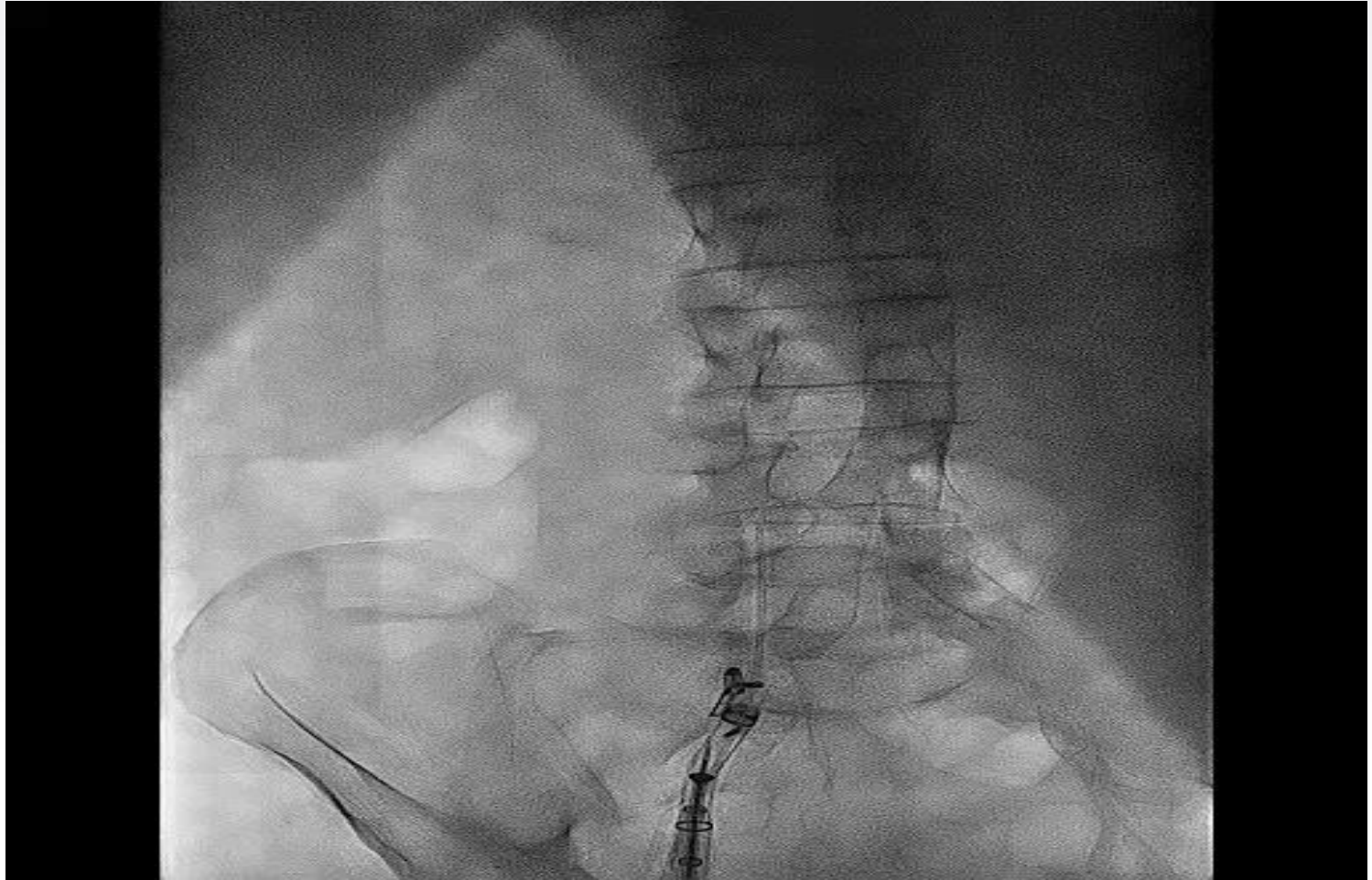
Introduce the Clip Coaxial in the Sheath



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

Introduce the Clip Coaxial in the Sheath



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

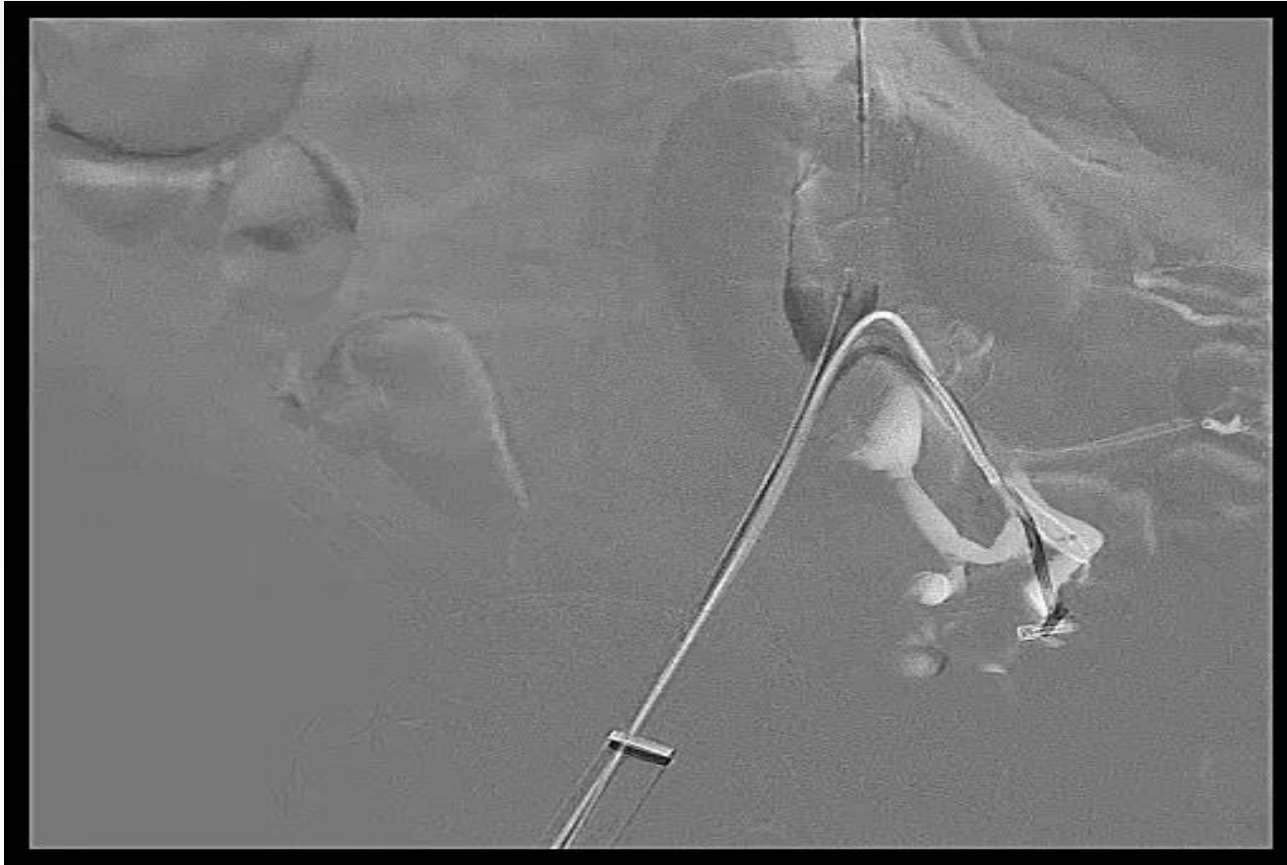
Distal Embolization of Clip Elements



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

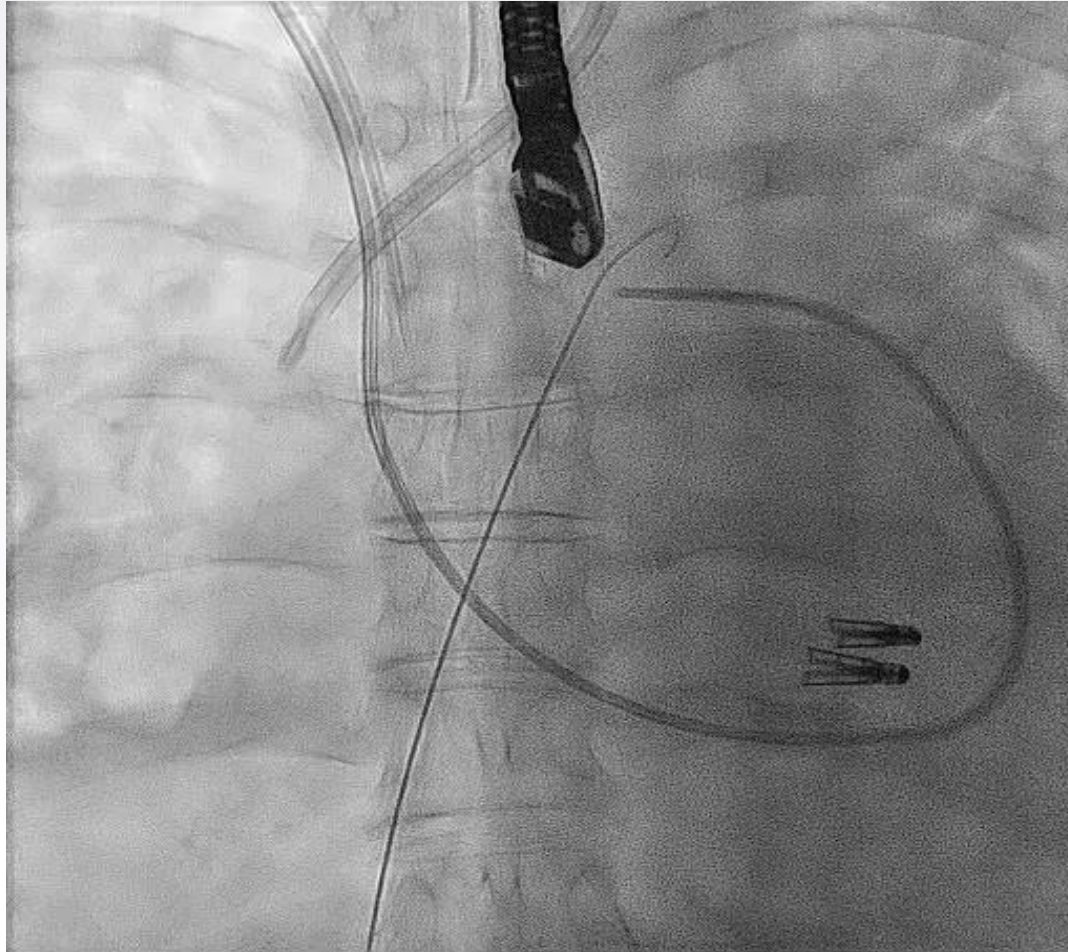
Don't leave any Piece behind



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

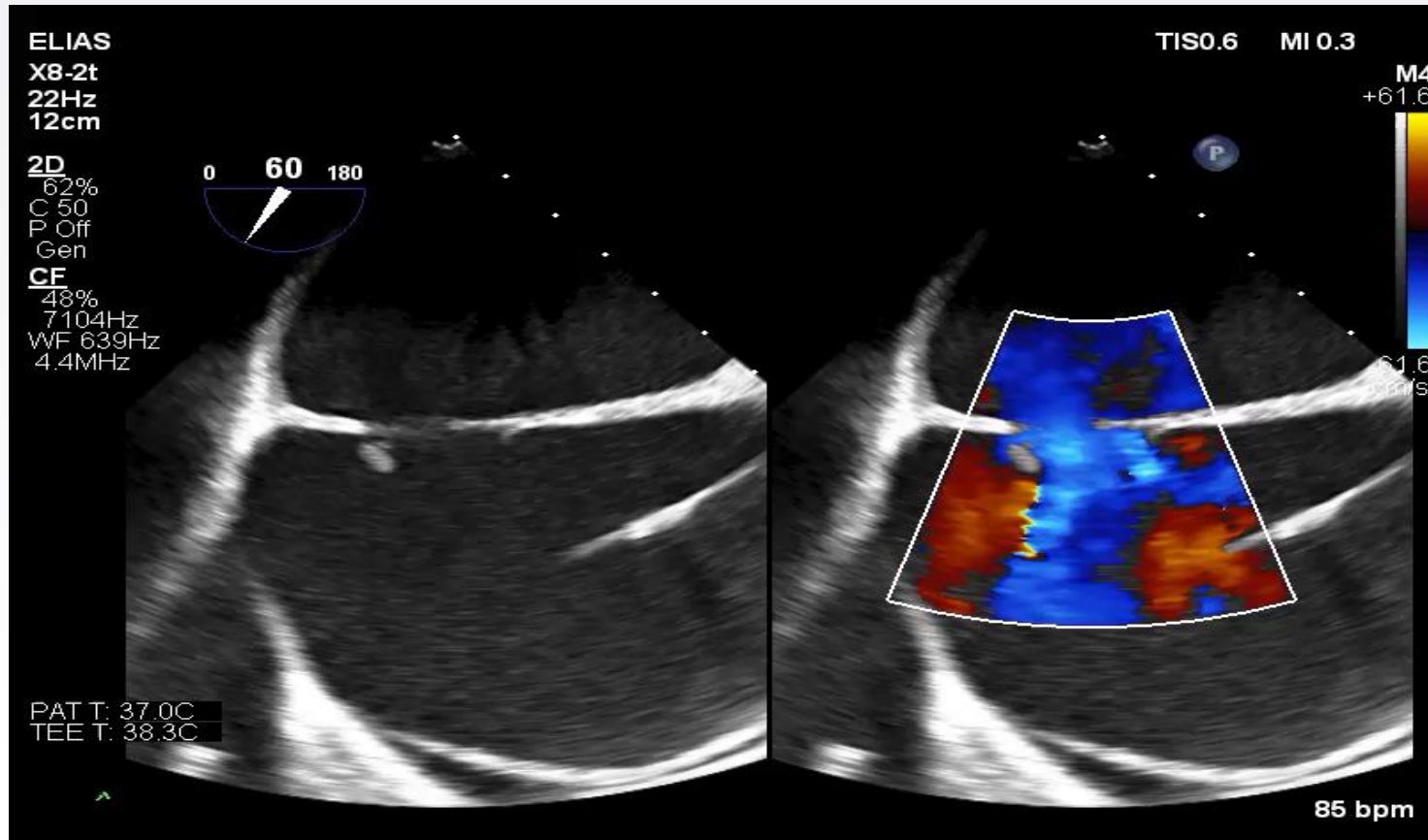
75 y/o female severe MR ,CHF Class III/IV, High Surgical Risk, previous extensive extensive vascular and surgical procedures for Pelvic AV malformations.
Only Access Trans Septal LEFT FEMORAL VEIN



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

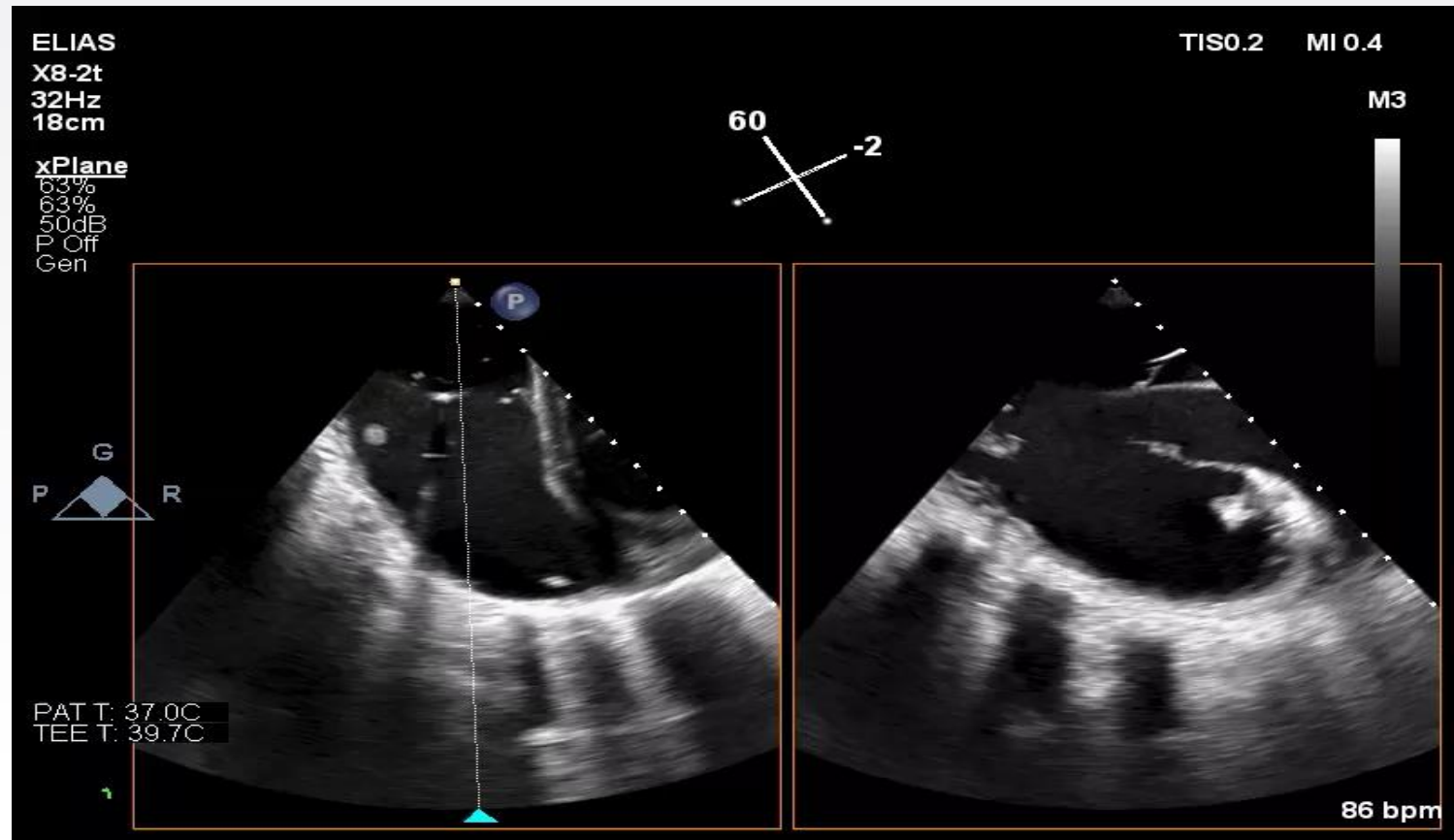
Post MitraClip Large Residual Shunt



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

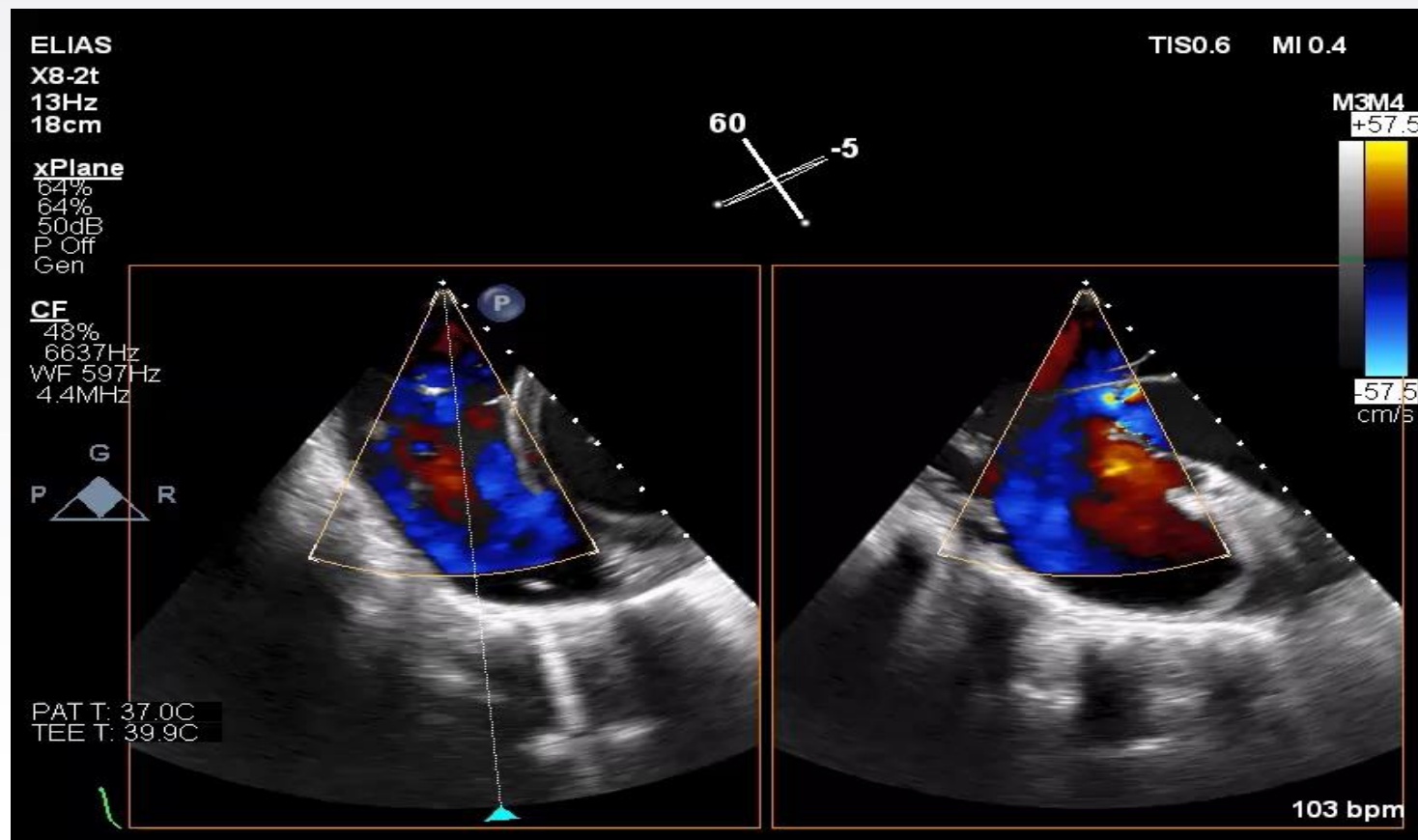
24 hours later: sat 90%, BPs 90, HR 110, Otherwise
“Stable”



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

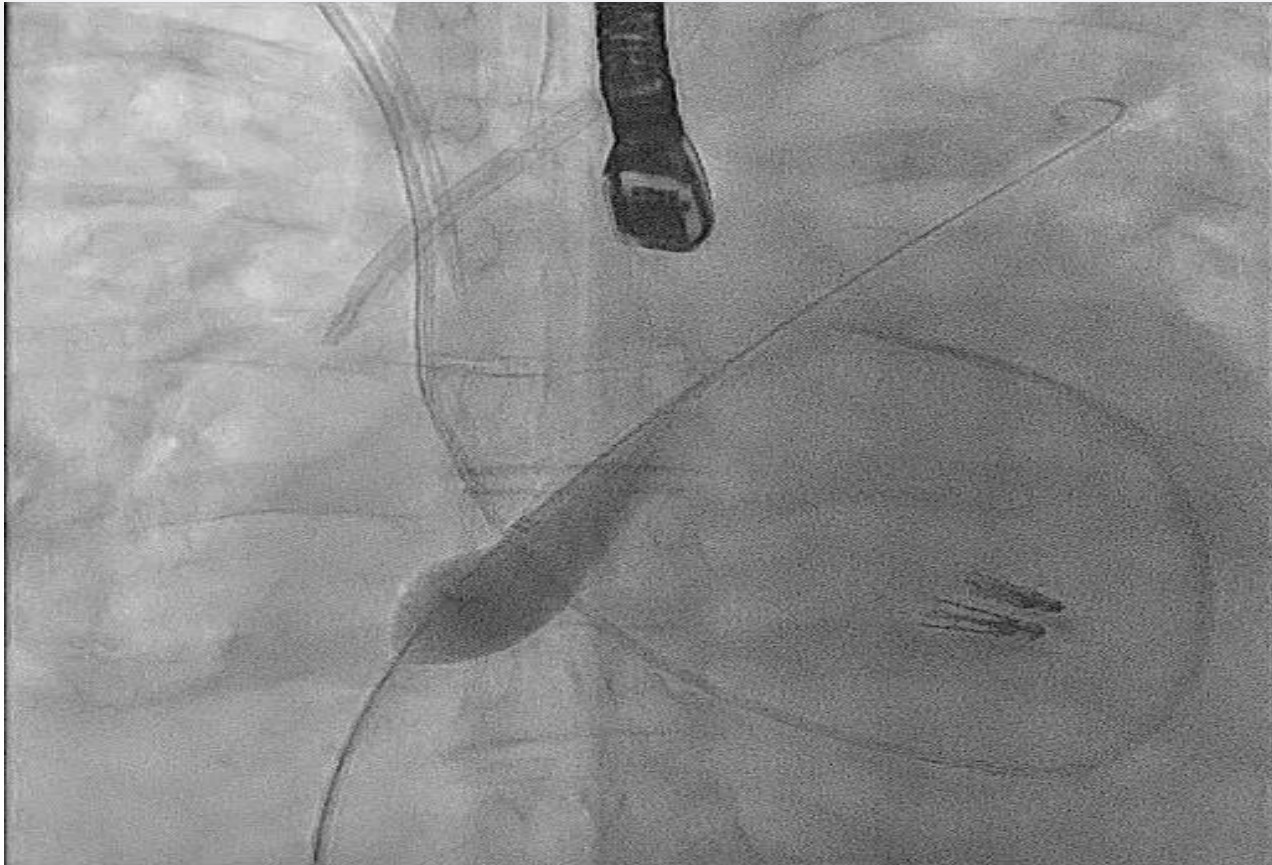
The question is : Close or Not ?



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

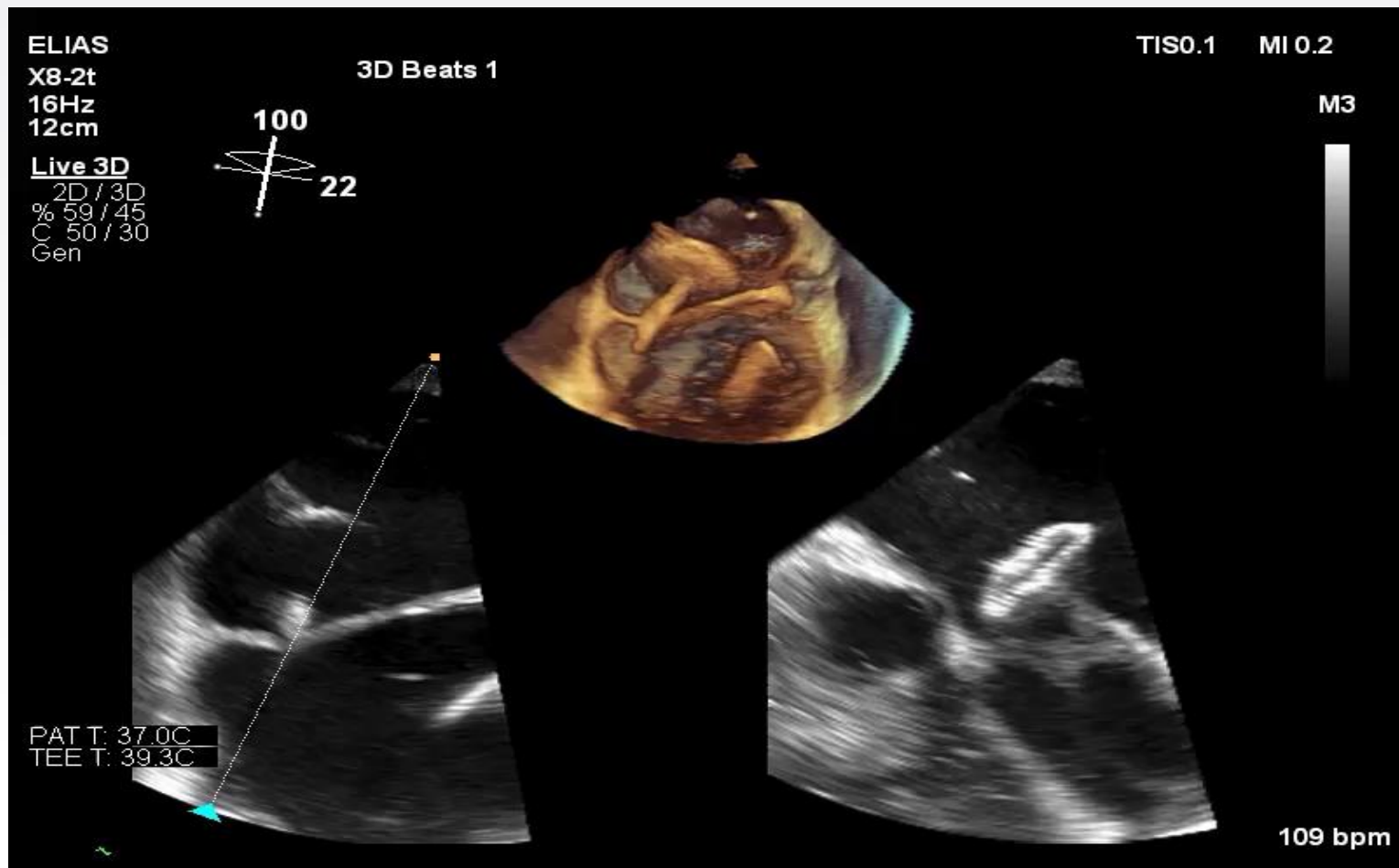
Close: Ballon Sizing



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

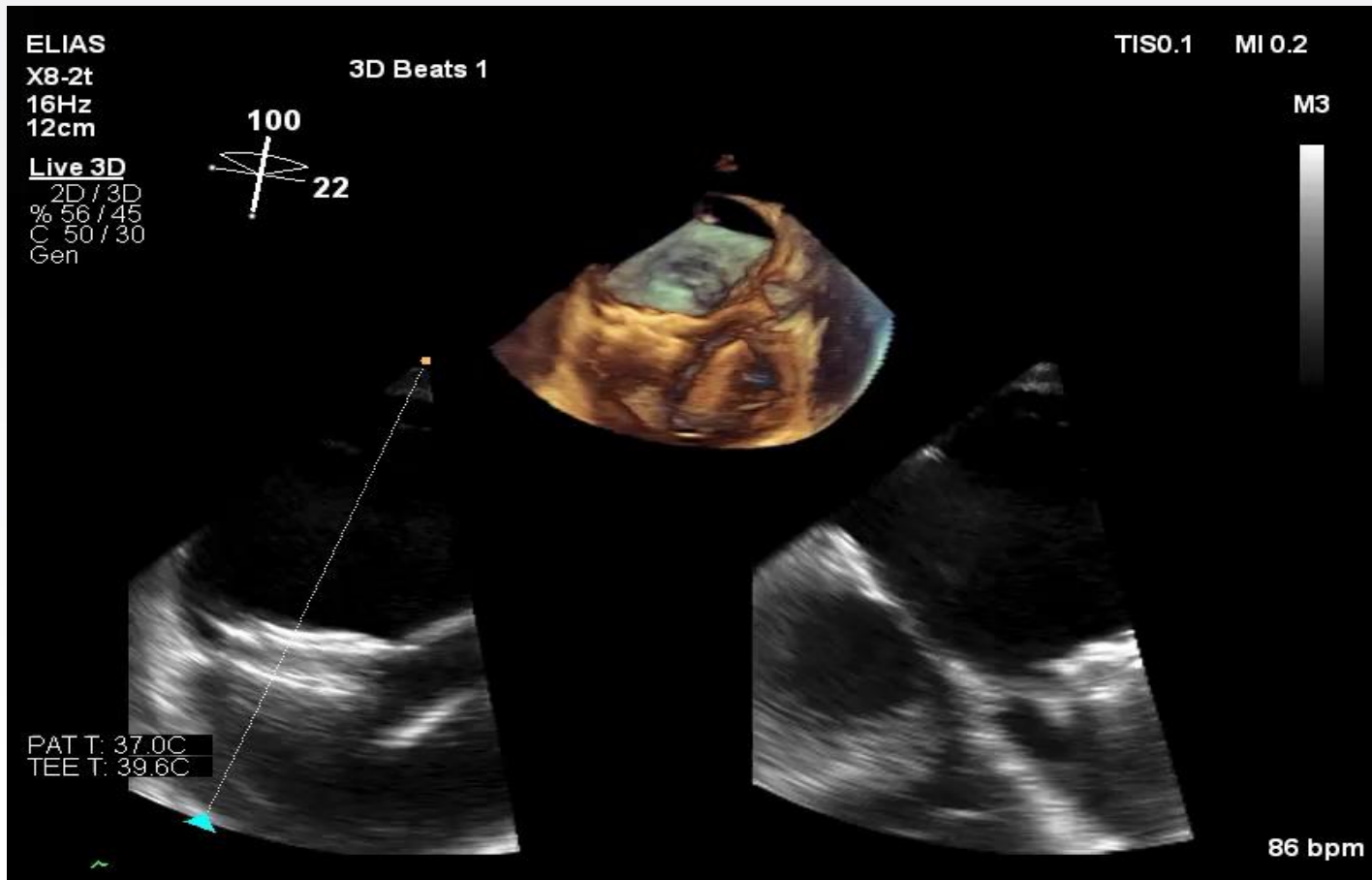
ASO Device Placement



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

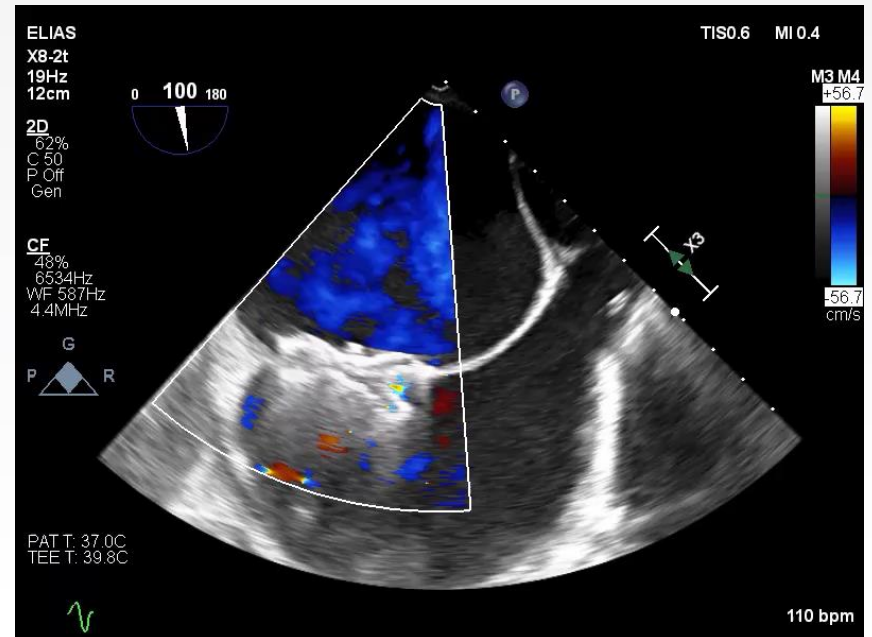
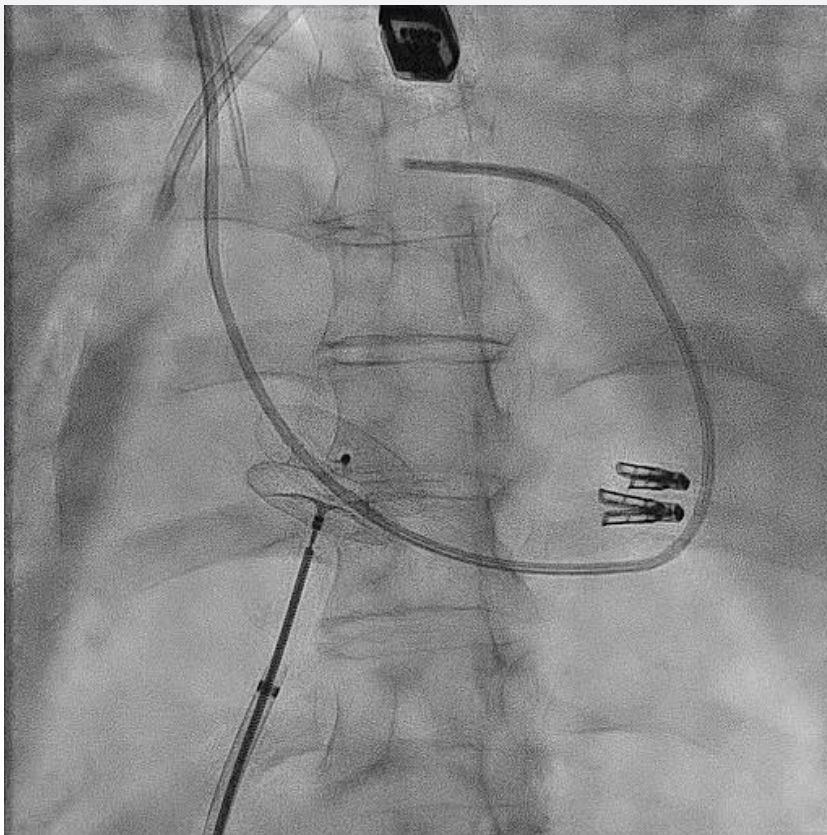
ASO : Device Placement



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

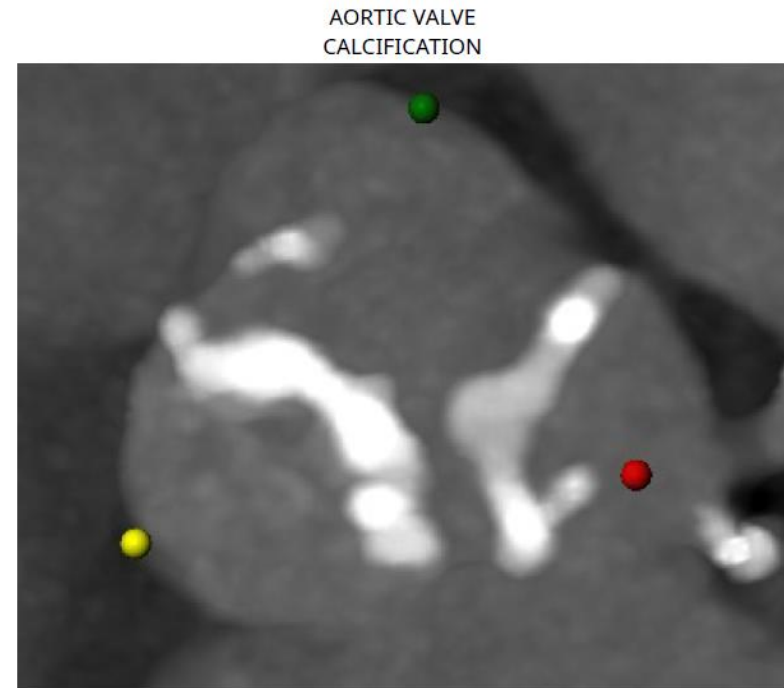
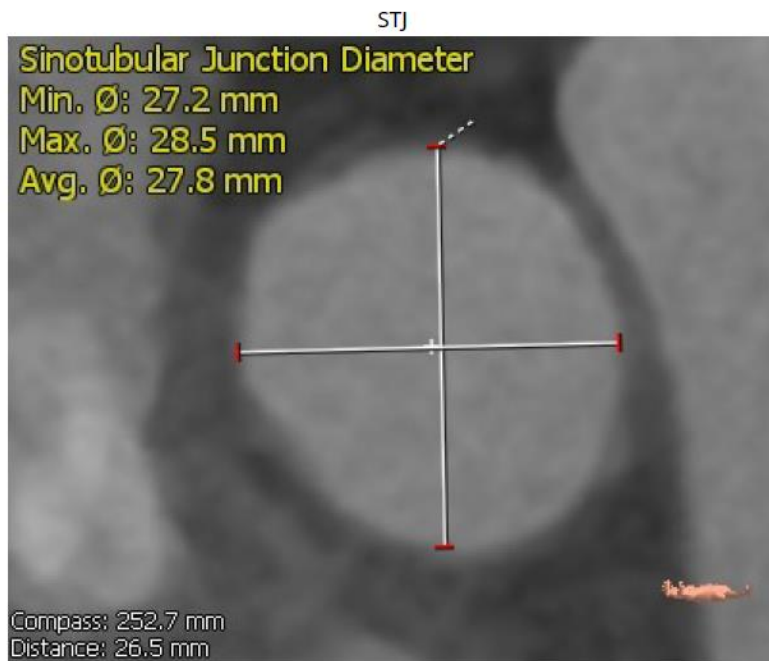
Device Release



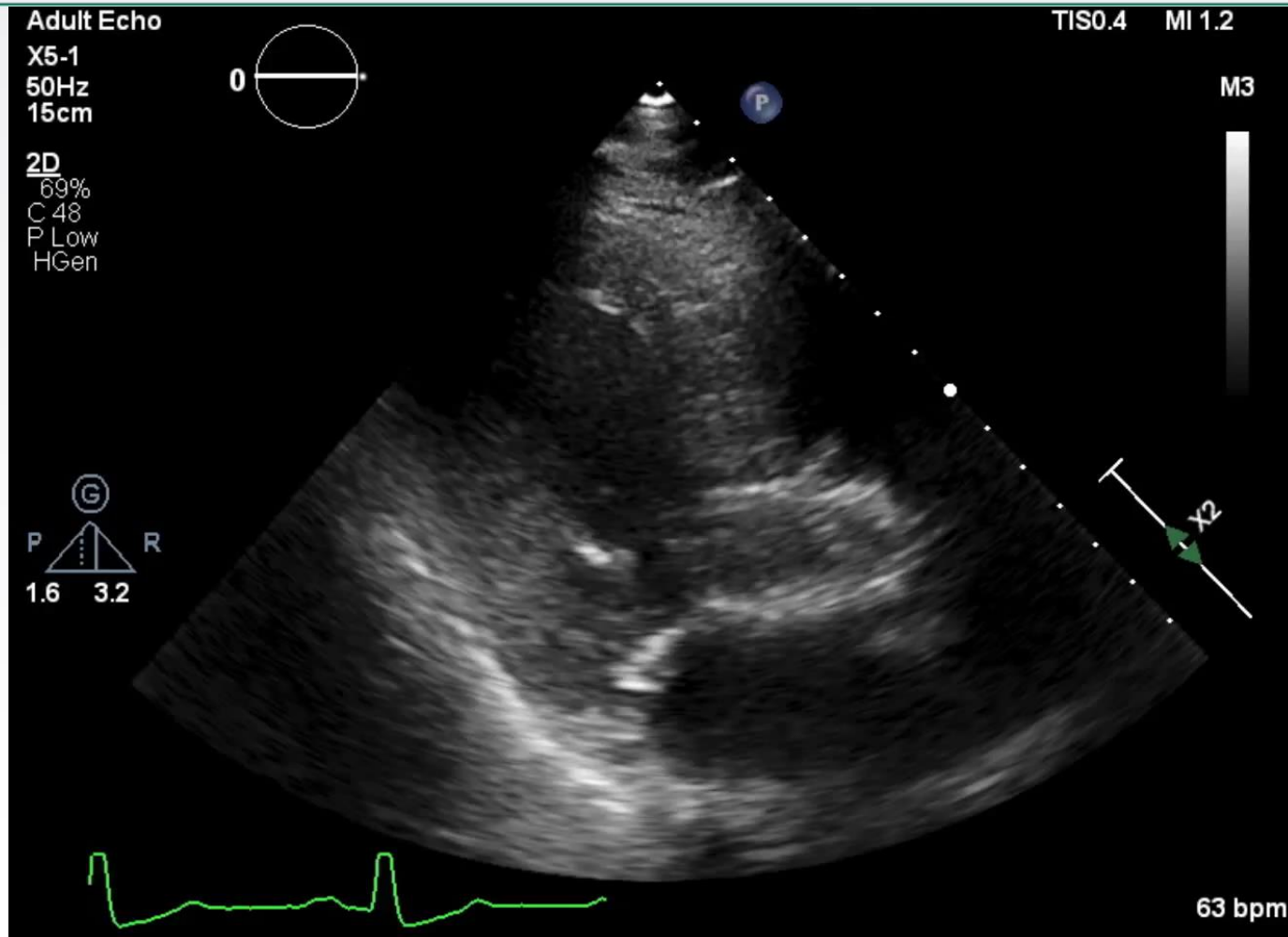
Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

Functional Bicuspid AV



Post TAVR Cordal SAM



Miami Cardiac & Vascular Institute

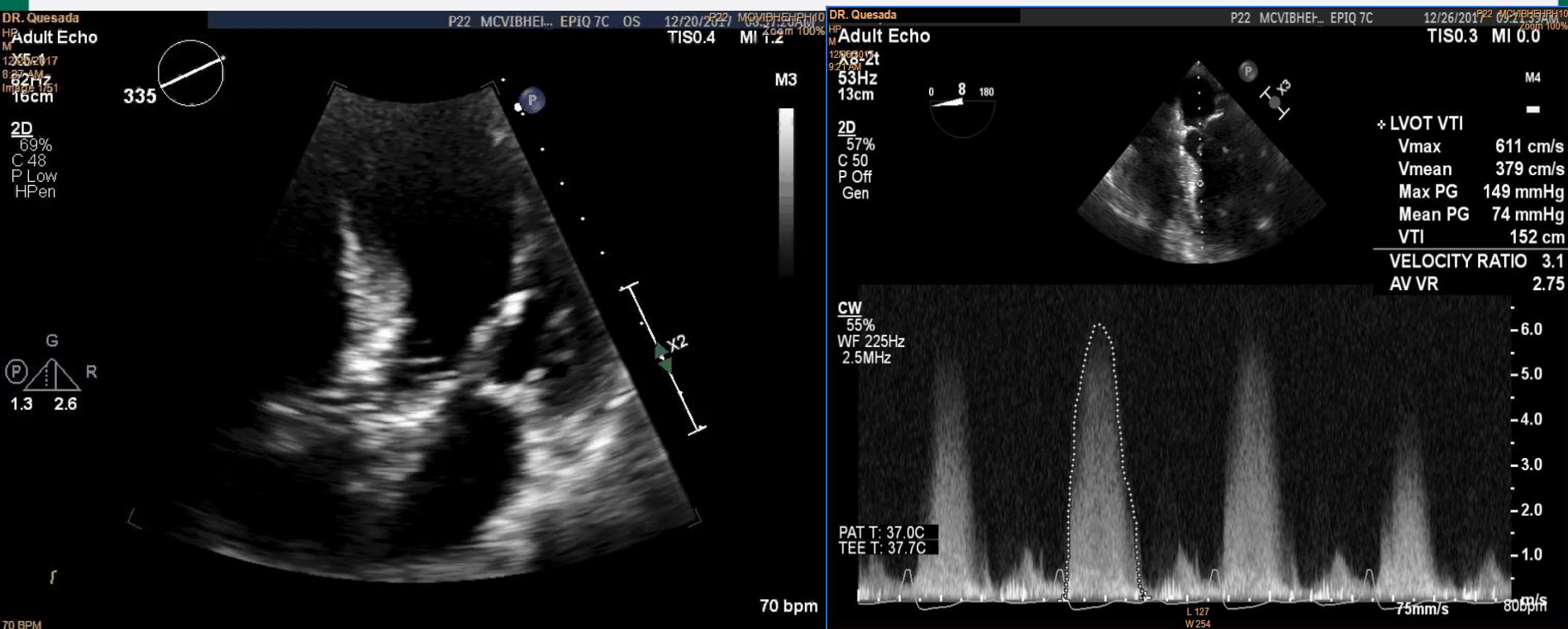
BAPTIST HEALTH SOUTH FLORIDA

TAVR

- Successful AVR with self expanding 29 Evolut R and a very calcified functional bicuspid aortic valve. Post procedure gradient was 2 mmHg and no Aortic Insufficiency.
- There is left ventricular obstruction with evidence of systolic anterior motion and a gradient of the left ventricular outflow tract of 40 mmHg.



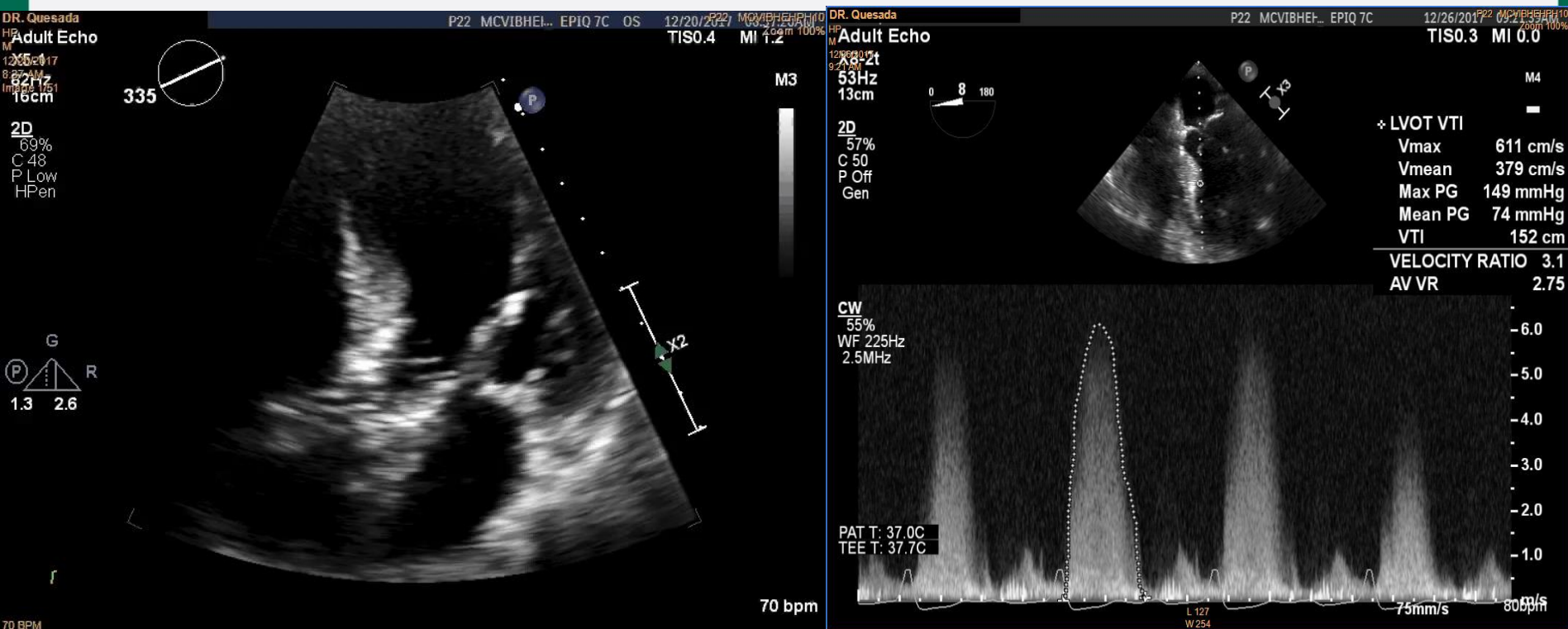
LVOT Obstruction



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

LVOT Obstruction



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

NOW WHAT?

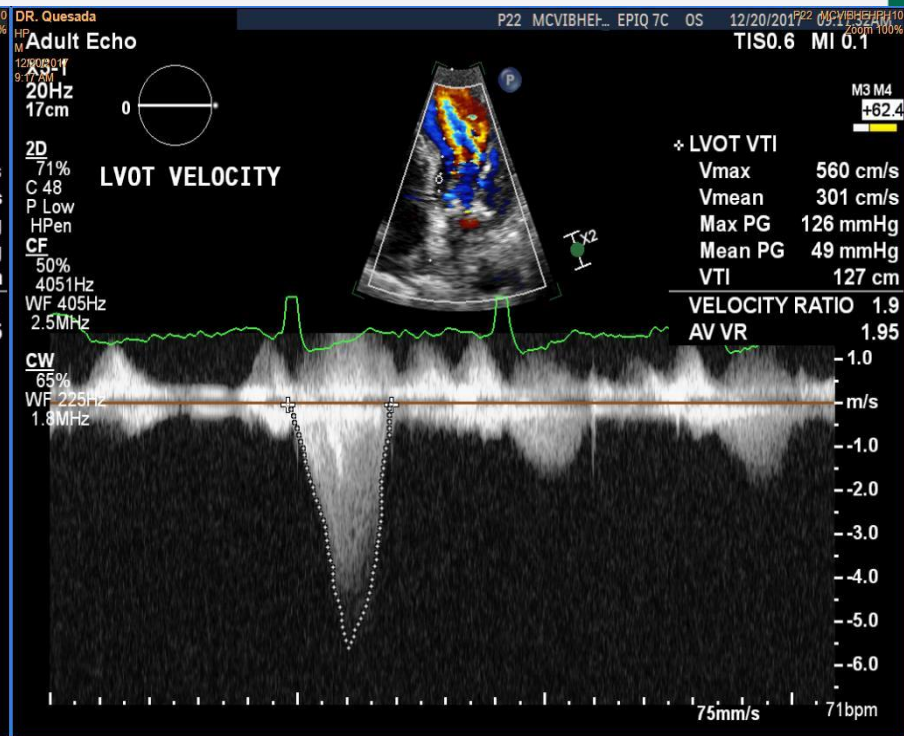
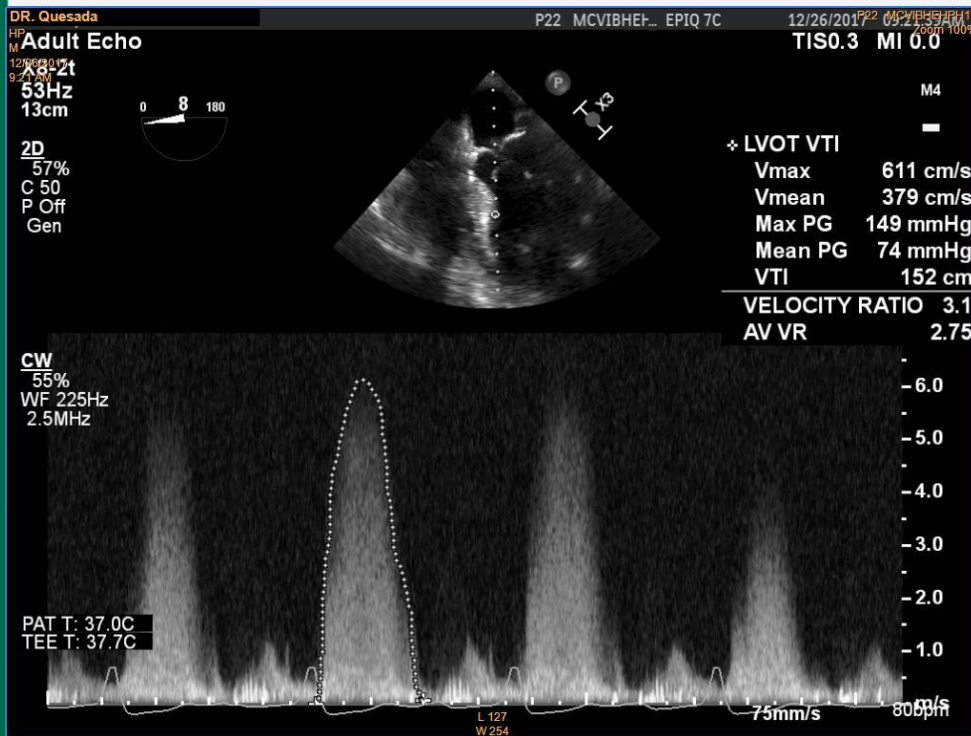


Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

- Do nothing?
- Alcohol septal ablation?
- Other?

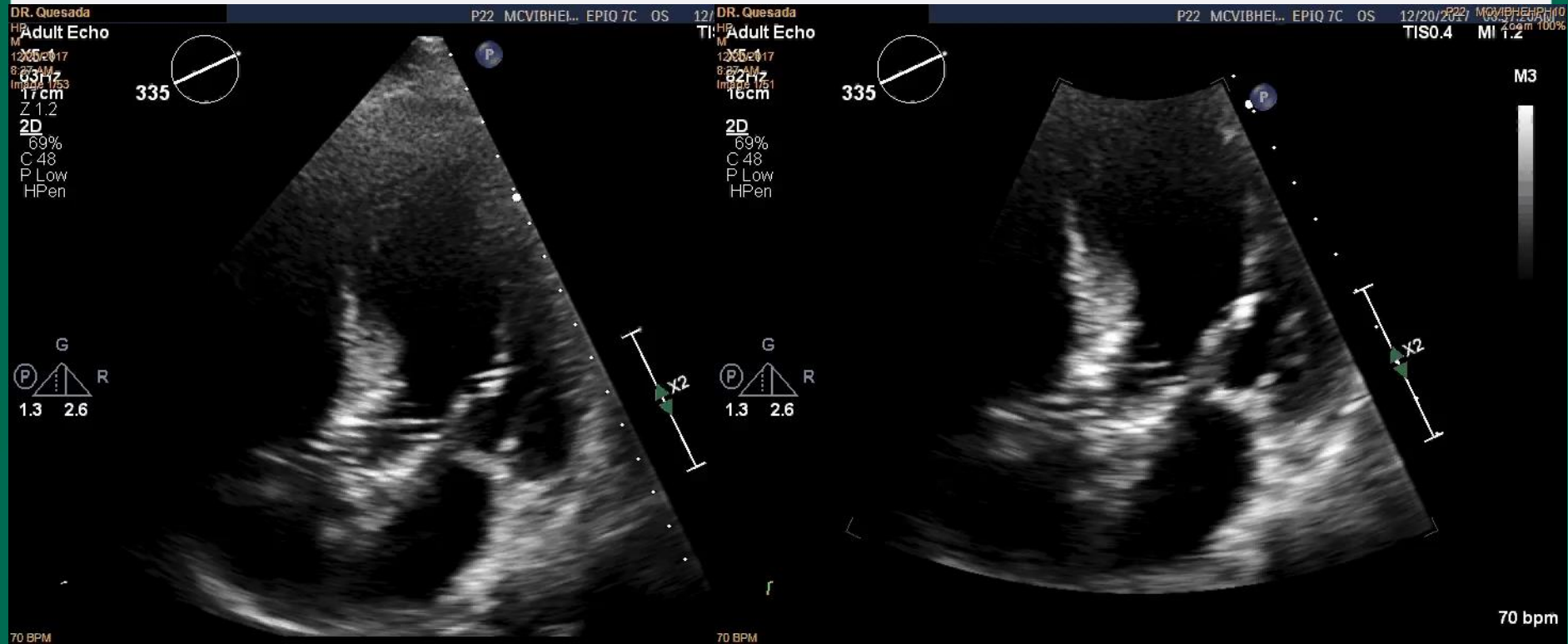




Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

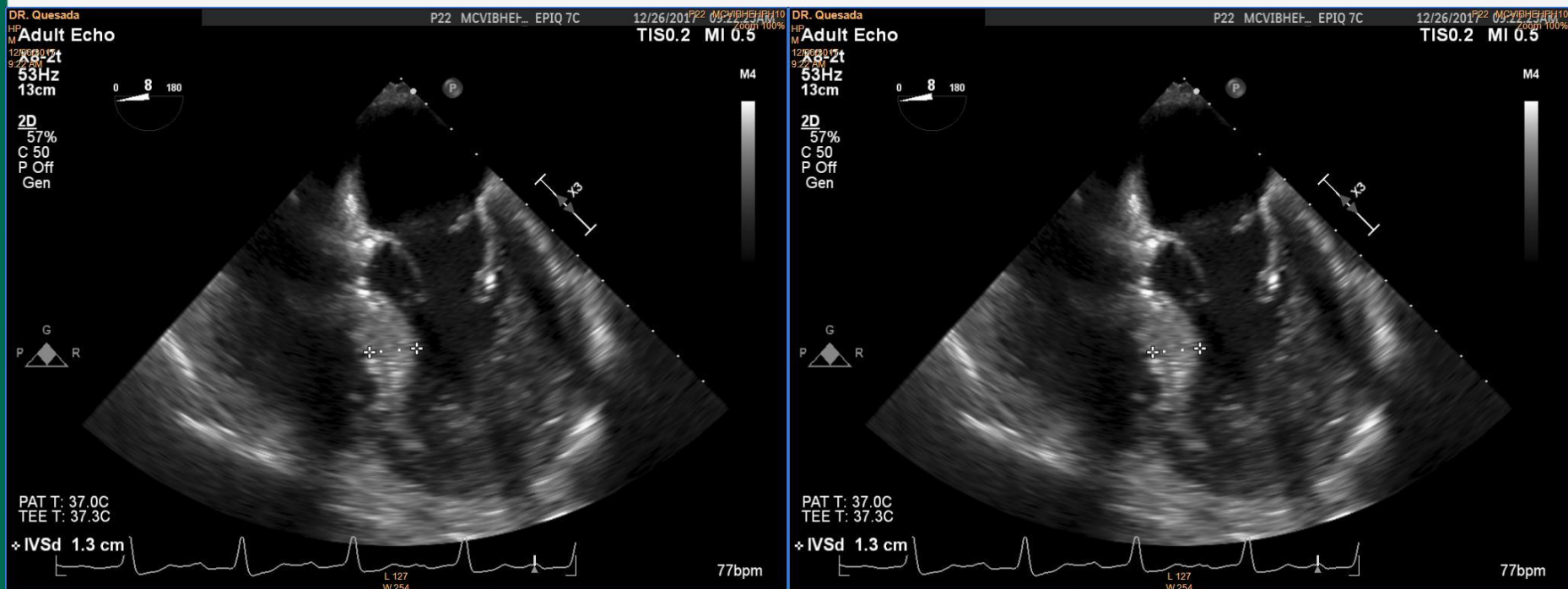
LVOT Obstruction SAM



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

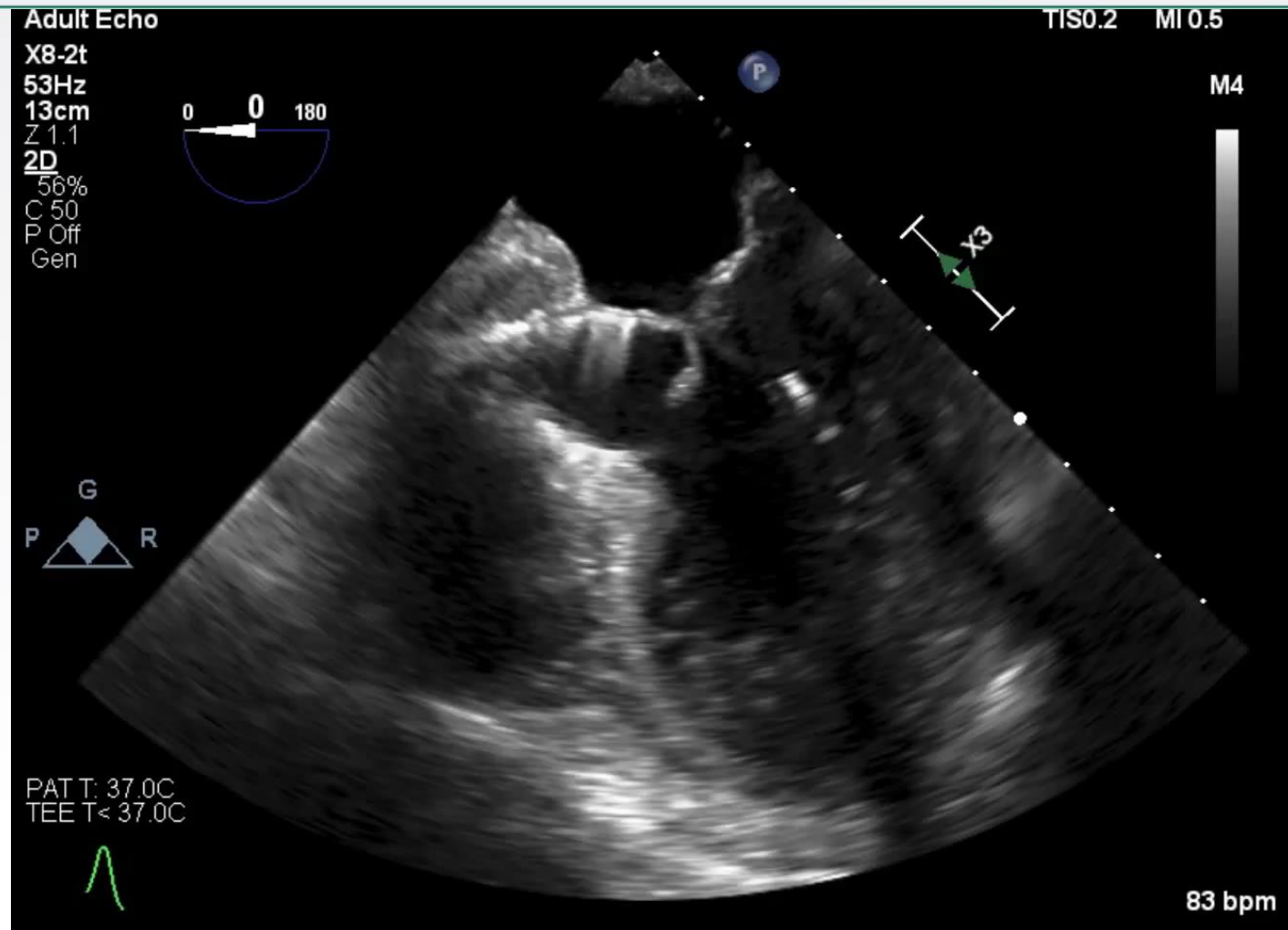
Septal Hypertrophy 1.3cm



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

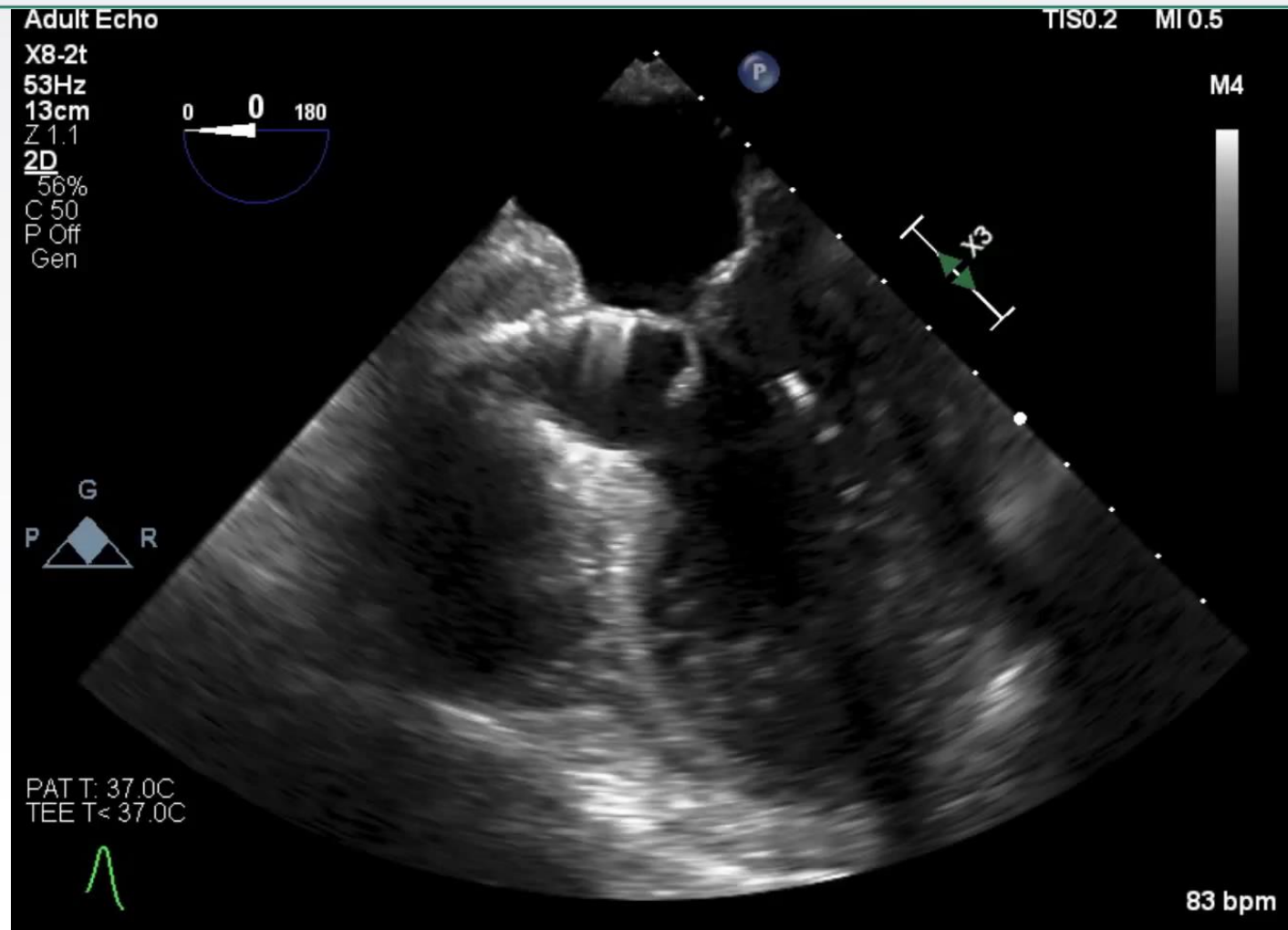
TEE SAM



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

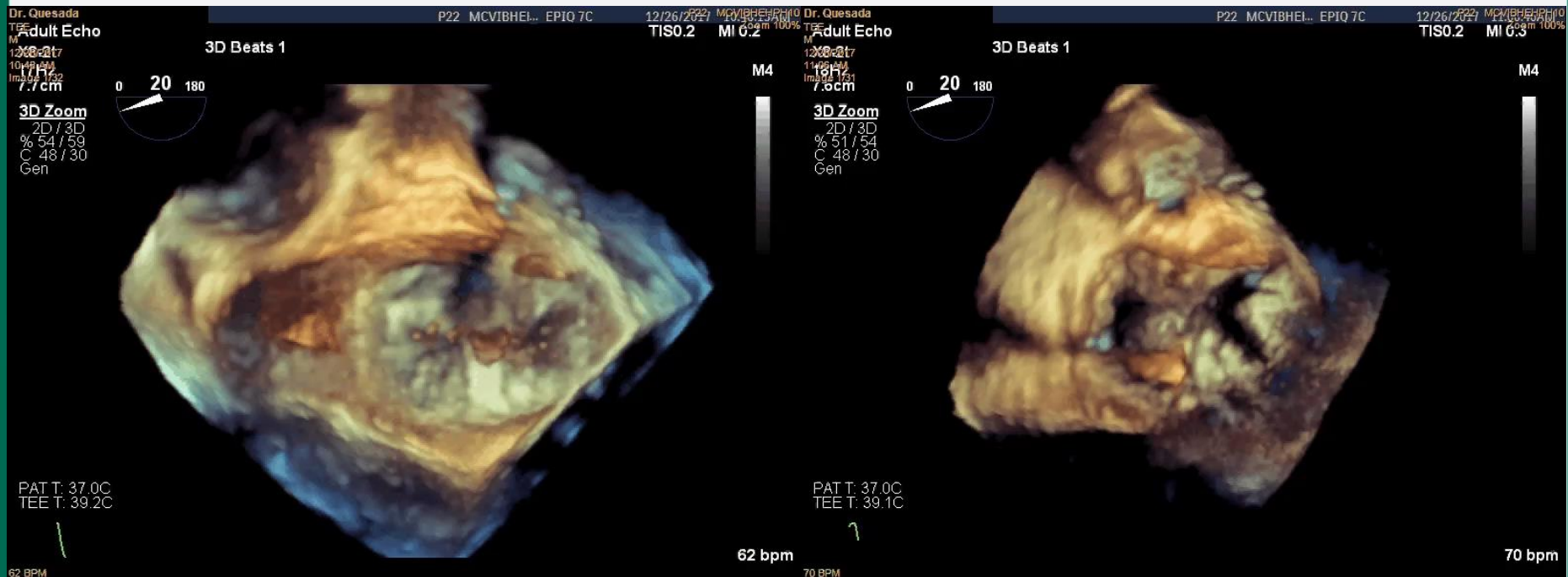
TEE SAM



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

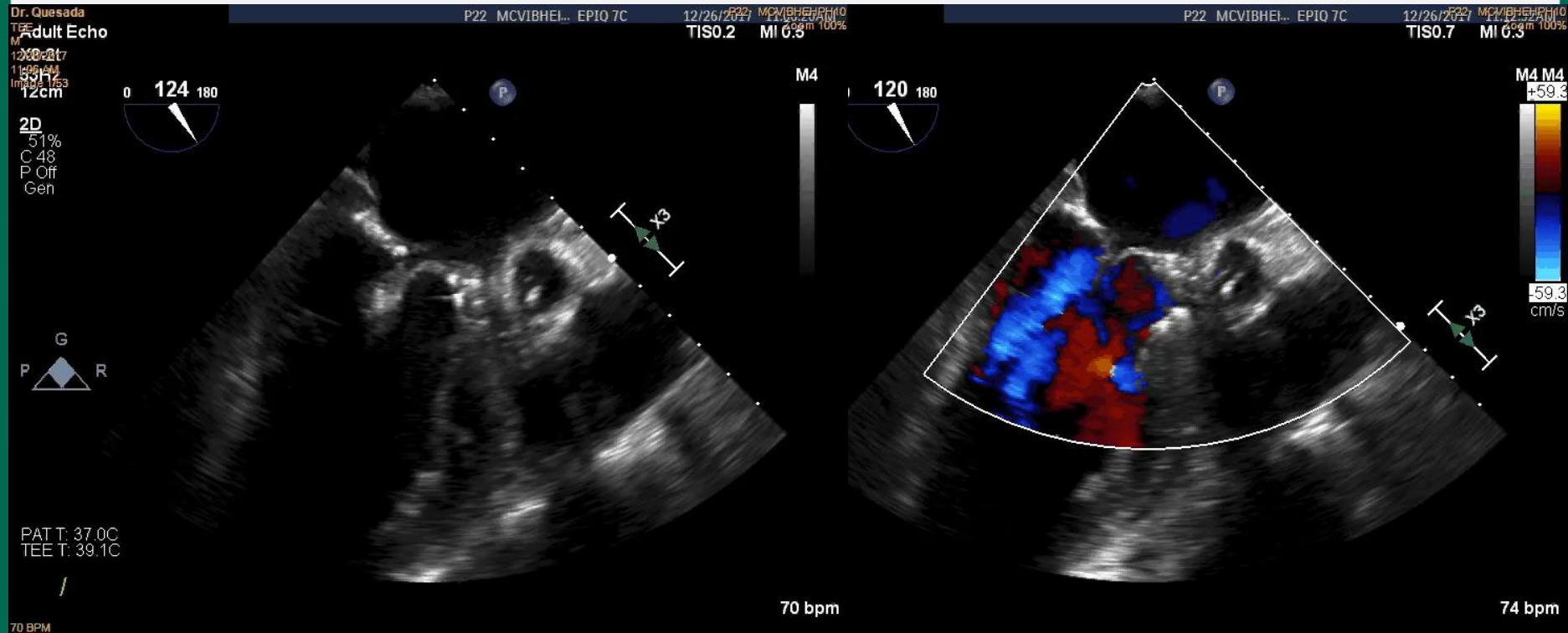
Relieve the SAM: MitraClip



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

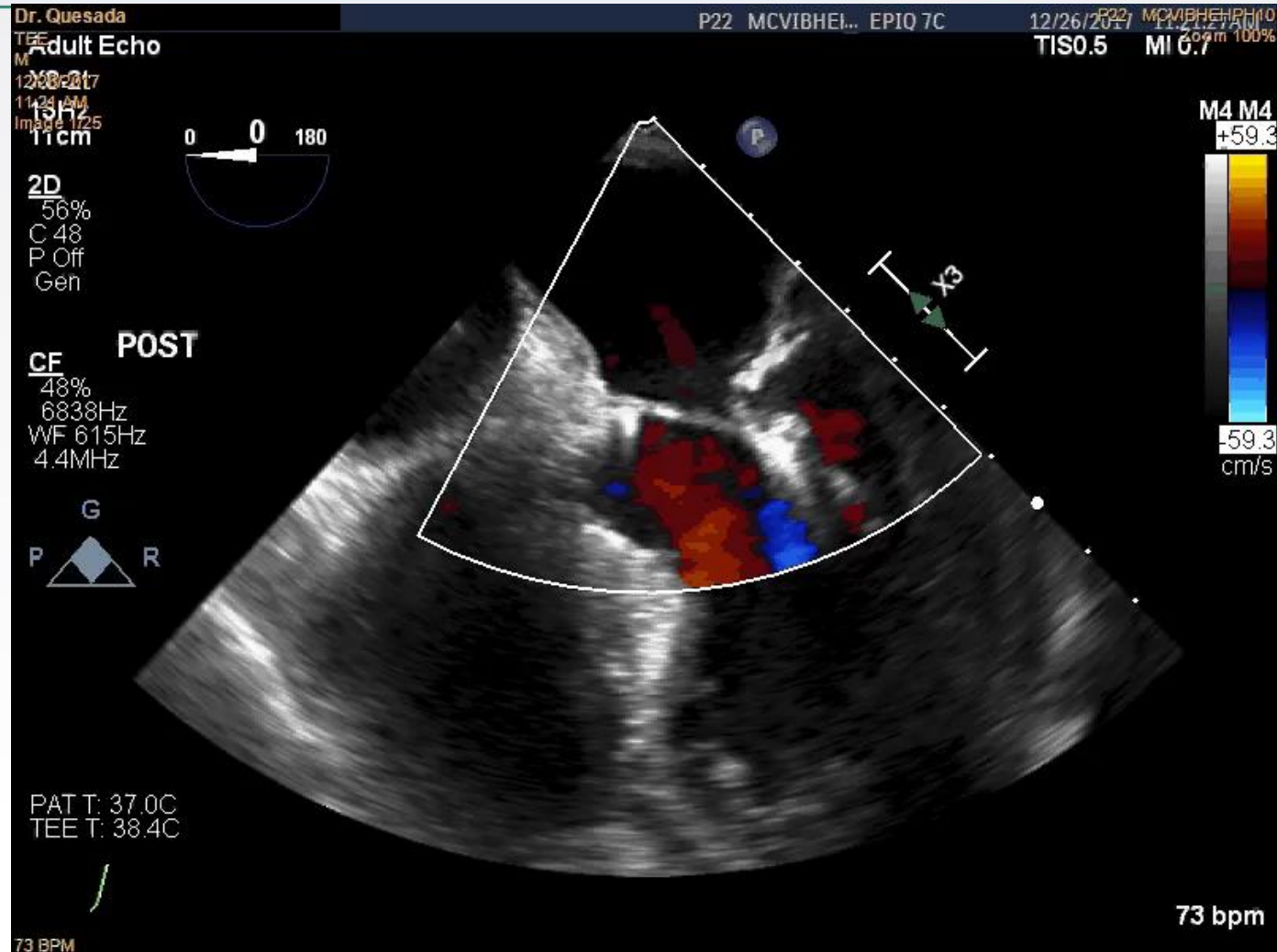
Post Release



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

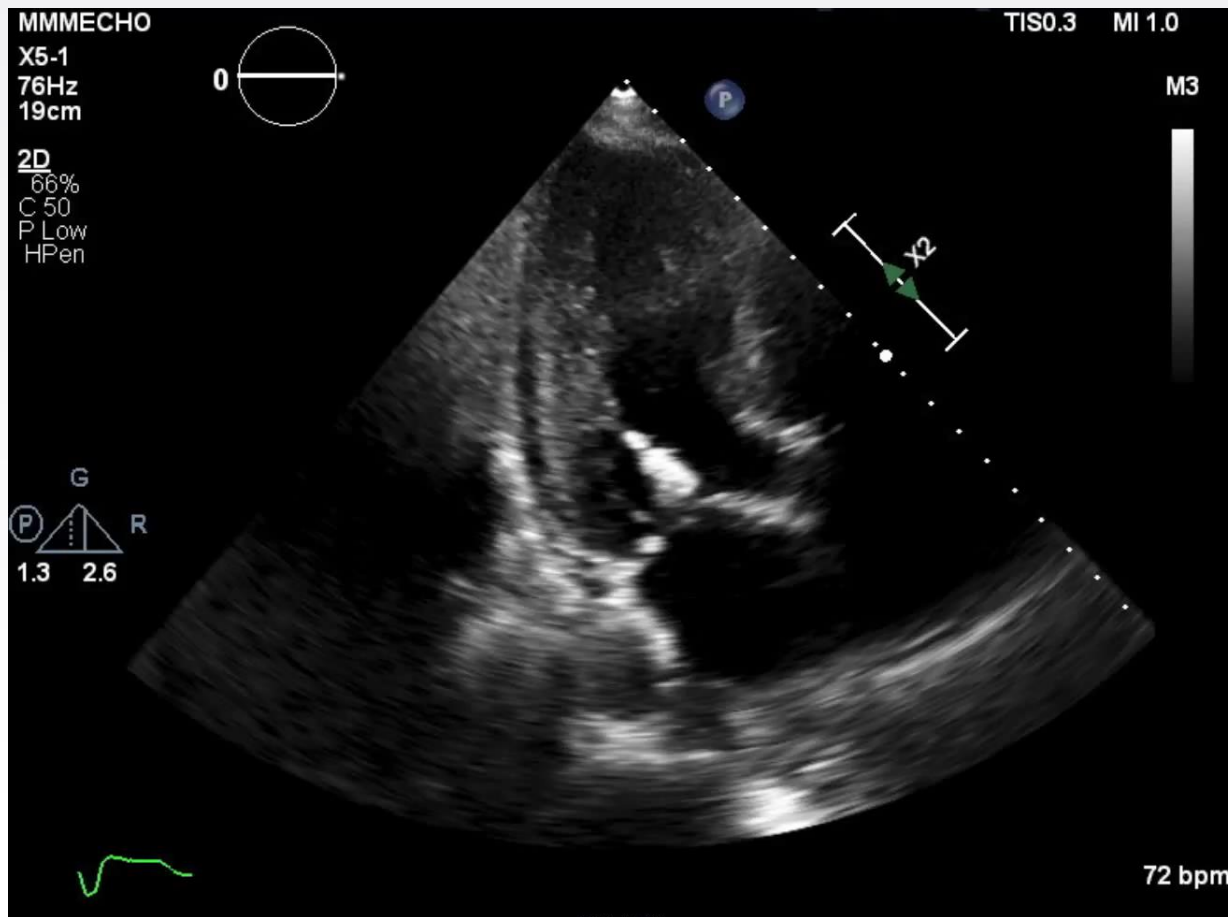
MitraClip post release



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

Final Result No SAM, No Gradient



Miami Cardiac & Vascular Institute

BAPTIST HEALTH SOUTH FLORIDA

Conclusions

- Mitral Valve Repair with MitraClip is a very Safe Procedure, but Complications may occur.
- Assessing the Complication properly is Key to a Successful Outcome.
- Imaging is Paramount in road mapping your strategy for a successful procedure.
- Adequate leaflet grasping is not always a guarantee of procedural success and long-term outcome since (SLDA) Single Leaflet Device Attachment can occur.
- Mitral Valve anatomy is predictive of the early and late results of the Mitral Valve repair with Mitral Clip.



Thank You!

