



La Mitraclip nel Trattamento dell' Insufficienza Mitralica: Indicazioni, Tecnica ed Outcome

Sfide in cardiologia clinica

10/11 marzo 2017

Mantova MaMu, Centro Congressi Mantova Largo di Porta Pradella, 1

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Epidemiologia dell'Insufficienza Mitralica

Epidemiologia dell'insufficienza mitralica

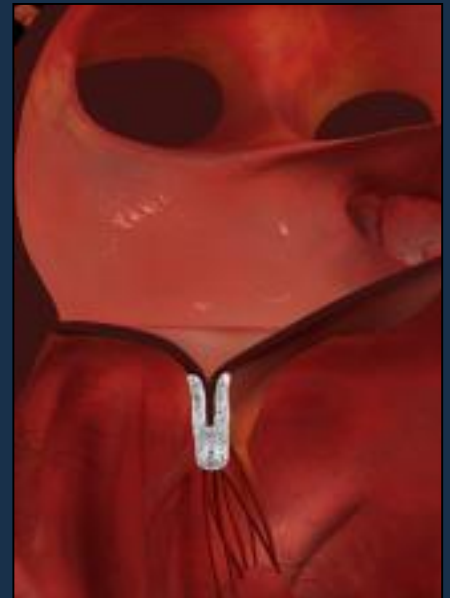
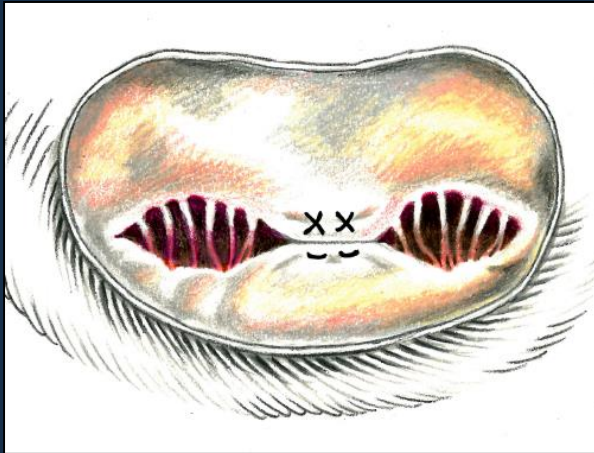
- L'insufficienza mitralica (IM) è la seconda valvulopatia più frequente nel mondo occidentale. Qualora il vizio mitralico risulti severo, **l'aspettativa di vita e la libertà da eventi** risultano fortemente compromesse. Nonostante le attuali linee guida siano ben chiare nell'indicare l'intervento chirurgico, riparativo o sostitutivo, come trattamento di scelta nei pazienti con IM severa, esistono tuttavia condizioni complesse in pazienti con IM severa e scompenso cardiaco (SC) in fase avanzata
- Nell'EuroHeart Survey viene evidenziato come il 50% di pazienti anziani, sintomatici per IM severa, non vengano sottoposti a chirurgia a causa dell'età o delle co-patologie. Per questo motivo sono stati sviluppati diversi dispositivi per effettuare una correzione dell'IM in maniera meno invasiva (percutanea) e ridurre i rischi legati alla chirurgia.
- IM significativa è presente in circa il 30% dei pazienti con pregresso infarto miocardico e nel 35% dei pazienti con SC cronico. Dati derivati da diversi studi osservazionali pubblicati in letteratura dimostrano come la mortalità raddoppi quando lo SC in stadio avanzato si associa alla presenza di severo rigurgito mitralico.
- La prevalenza di insufficienza almeno moderata negli individui più giovani di 50 anni è inferiore all'1%, mentre viene identificata in 1 individuo su 10 oltre i 70 anni.

Storia naturale dell'insufficienza mitralica

- Le forme più comuni di insufficienza mitralica nei pazienti sottoposti a intervento chirurgico nei paesi occidentali sono la **forma degenerativa** (60-70% dei casi), seguita dalla **forma funzionale ischemica** (20%), **endocardite** (2-5%), **reumatica** (2-5%), e **altre forme** (1%).
- La storia naturale e i risultati clinici nei pazienti trattati in terapia medica o con intervento chirurgico differiscono nel caso di IM funzionale o degenerativa
- Il tasso di mortalità annuo nei pazienti con IM degenerativa significativa varia dall'1% al 9%. La mortalità è più alta nei pazienti con dilatazione ventricolare sinistra e nei pazienti sintomatici (classe NYHA III o IV).
- Per quanto riguarda l'IM funzionale, numerosi studi osservazionali hanno mostrato un aumento della mortalità nei pazienti con scompenso cardiaco in presenza di rigurgito mitralico significativo.

Catheter-Based Mitral Valve Repair

MitraClip® System



Indicazioni all'impianto di Mitraclip

Endovascular Valve Edge-to-Edge REpair
Study (EVEREST II)

Randomized Clinical Trial:

Primary Safety and Efficacy Endpoints

Ted Feldman, Laura Mauri, Elyse Foster, Don Glower on
behalf of the EVEREST II Investigators

Table 1 – Major criteria for inclusion and exclusion of the patients undergoing percutaneous repair of mitral regurgitation with MitraClip system according to the EVEREST II trial.

Criteri di inclusione
Età ≥ 18 anni
Insufficienza mitralica moderata-severa (3+) o severa (4+) sintomatica o asintomatica ma con frazione d'eiezione del VS <60% o diametro tele-sistolico ventricolare sinistro >45 mm
Candidati ad alto rischio per chirurgia della valvola mitrale
Presenza di sufficiente tessuto dei lembi per una coaptazione meccanica
Morfologia valvolare non reumatica né endocarditica
Cateterismo transettale fattibile.
Criteri di esclusione
Infarto miocardico acuto nelle precedenti 12 settimane
Necessità di altra chirurgia cardiaca
Area mitralica <4.0 cm ²
Se è presente flail: <i>flail width</i> ≥15 mm <i>flail gap</i> ≥10 mm
Se è presente <i>tethering</i> : <i>coaptation depth</i> ≥11 mm <i>coaptation length</i> <2 mm
Severe calcificazioni dell'anulus mitralico
Qualunque anatomia dei lembi che può precludere l'impianto e il corretto posizionamento della clip o una sufficiente riduzione del rigurgito mitralico.
Instabilità emodinamica (PAS <90 mmHg), shock cardiogeno o necessità di supporto con inotropi o contro pulsatore aortico.
Cardiomiopatia ipertrofica e SAM
Valutazione ecocardiografica di masse intracardiache, trombi o vegetazioni.
Endocardite in fase attiva o pregressa
Malattia reumatica attiva o pregressa
Difetto interatriale noto, sia sottoposto a riparazione o no
PFO associato a sintomi di ischemia cerebrale o quando precedentemente riparato
Aneurisma del setto interatriale che possa interferire con puntura transettale
Storia di ictus cerebri o TIA documentato nei 6 mesi antecedenti
Controindicazioni all'esecuzione di ecocardiogramma trans-esofageo.

EVEREST II Randomized Clinical Trial

Baseline Demographics & Co-morbidities

	Device (%) n=184	Control (%) n=95	<i>P</i>
Age (mean)	67.3 years	65.7 years	0.32
Male	62.5	66.3	0.60
Congestive heart failure	90.8	77.9	<0.01
Coronary artery disease	47.0	46.3	>0.99
Myocardial infarction	21.9	21.3	>0.99
Angina	31.9	22.2	0.12
Atrial fibrillation	33.7	39.3	0.42
Cerebrovascular disease	7.6	5.3	0.62
Peripheral vascular disease	6.5	11.6	0.17
Cardiomyopathy	17.9	14.7	0.61
Hypercholesterolemia	61.0	62.8	0.80
Hypertension	72.3	78.9	0.25
Moderate to severe renal disease	3.3	2.1	0.72
Diabetes	7.6	10.5	0.50
Previous cardiovascular surgery	22.3	18.9	0.54
MR Severity: 3+ to 4+	95.7	92.6	0.48
MR Etiology: Degenerative / Functional	73 / 27	73 / 27	0.81

EVEREST II Randomized Clinical Trial

Additional Analyses

Intention to Treat

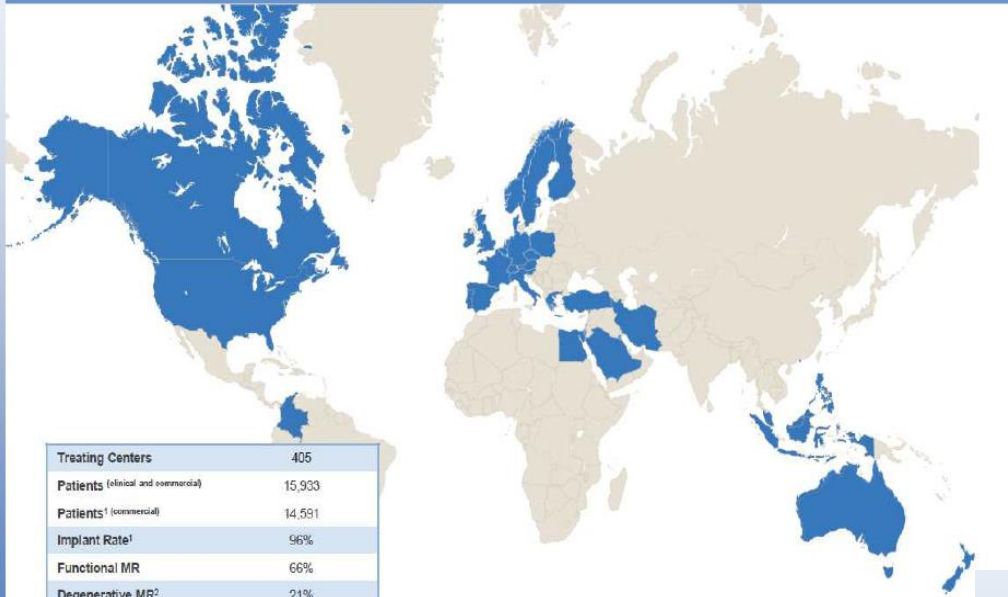
- Safety
 - Major Adverse Event Rate at 30 days
- Effectiveness
 - Freedom from the combined outcome of death, MV surgery >90 days or re-operation for valve dysfunction >90 days post Index procedure, and MR >2+ at 12 months

Clinical Benefit (per protocol cohort)

- MR Severity
- Left Ventricular Function
- NYHA Functional Class
- Quality of Life (SF-36 Survey)

MitraClip Therapy

Current Global Adoption



Treating Centers	405
Patients (clinical and commercial)	15,933
Patients ¹ (commercial)	14,591
Implant Rate ¹	96%
Functional MR	66%
Degenerative MR ²	21%
Mixed	13%

1. First-time procedures only. Includes commercial patients, ACCESS I and ACCESS II patients
2. Etiology not inclusive of U.S. cases as of 11/4/2014



In Italia attivi 47 centri

A Mantova:
Primo impianto nel Nov 2014
N 5 pazienti trattati

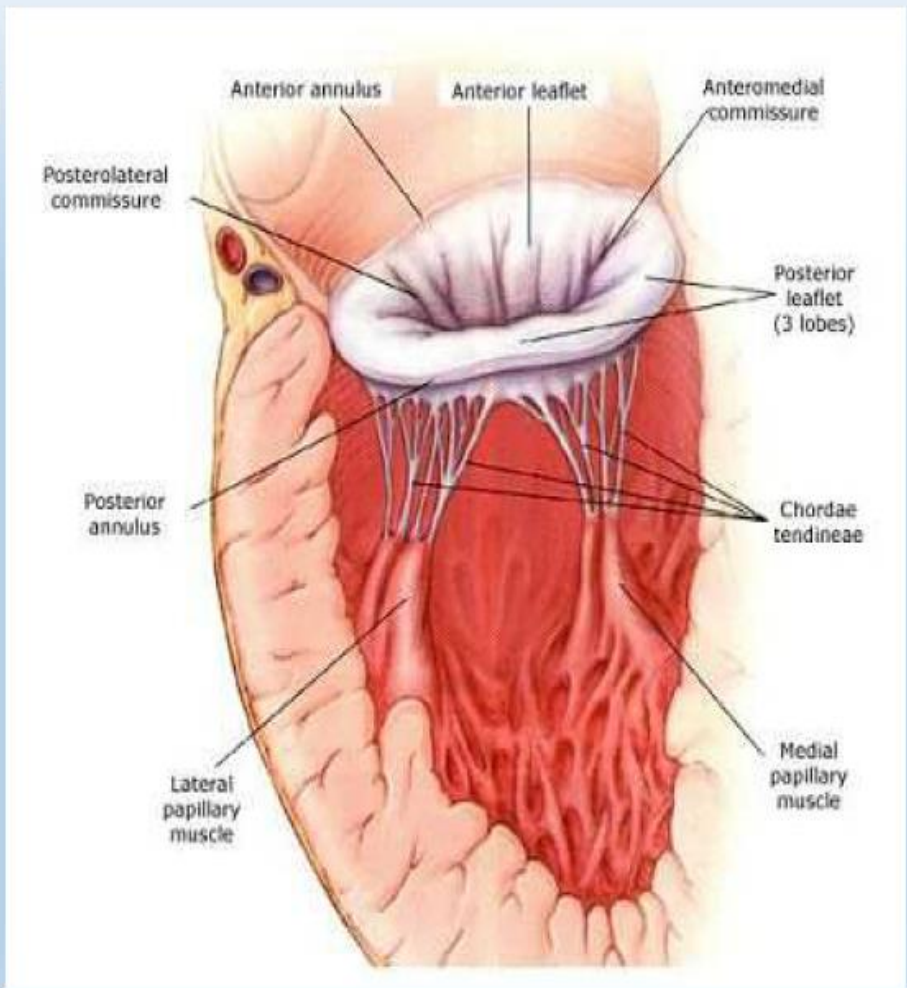
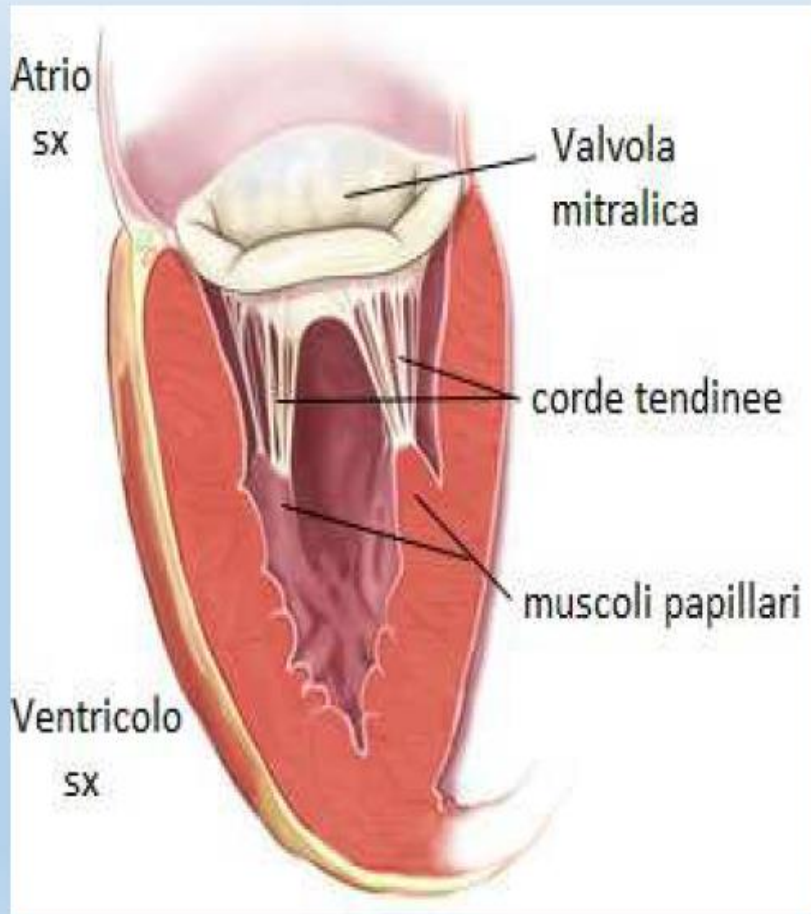
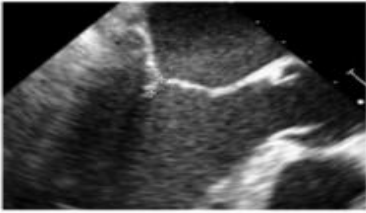

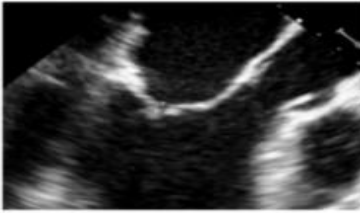
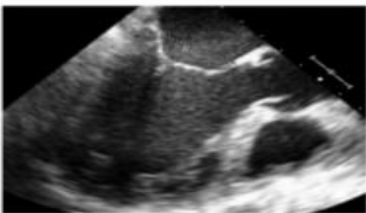
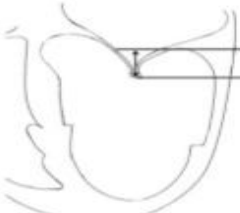




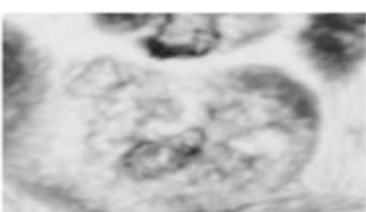
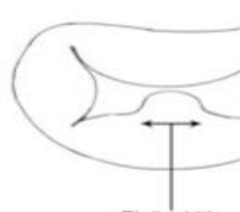
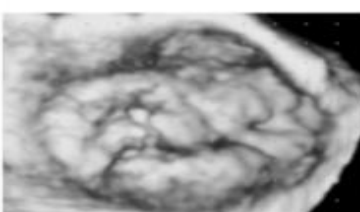


Tabella III - Tabella illustrativa dei criteri anatomici valvolari di inclusione dello studio EVEREST. Al centro l'immagine schematica ed il parametro valutato, sulla sinistra una immagine ecocardiografica di una valvola con anatomia favorevole e, a destra, una non favorevole.

Anatomia favorevole	Criteri Anatomici EVEREST	Anatomia non favorevole
	 <p>Coaptation length $\geq 2\text{mm}$</p>	
	 <p>Coaptation depth $< 11\text{mm}$</p>	
	 <p>Flail Gap $< 10\text{mm}$</p>	
	 <p>Flail width $< 15\text{mm}$</p>	

EDGE to EDGE

L'IM deve essere corretta suturando assieme i lembi mitralici soltanto laddove il rigurgito lo richiede. In particolare il margine libero del lembo malato deve essere ancorato al corrispondente margine del lembo opposto dove è localizzato il jet. In questo caso si creerà una valvola a doppio orificio. Se il jet è paracommissurale si creerà una valvola a singolo orificio ridotto.

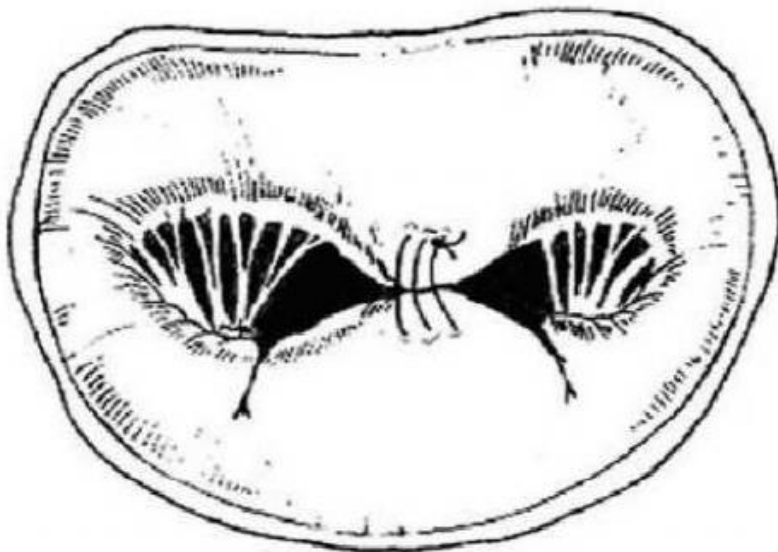


Figure 1. The "edge-to-edge" technique used as a double orifice repair

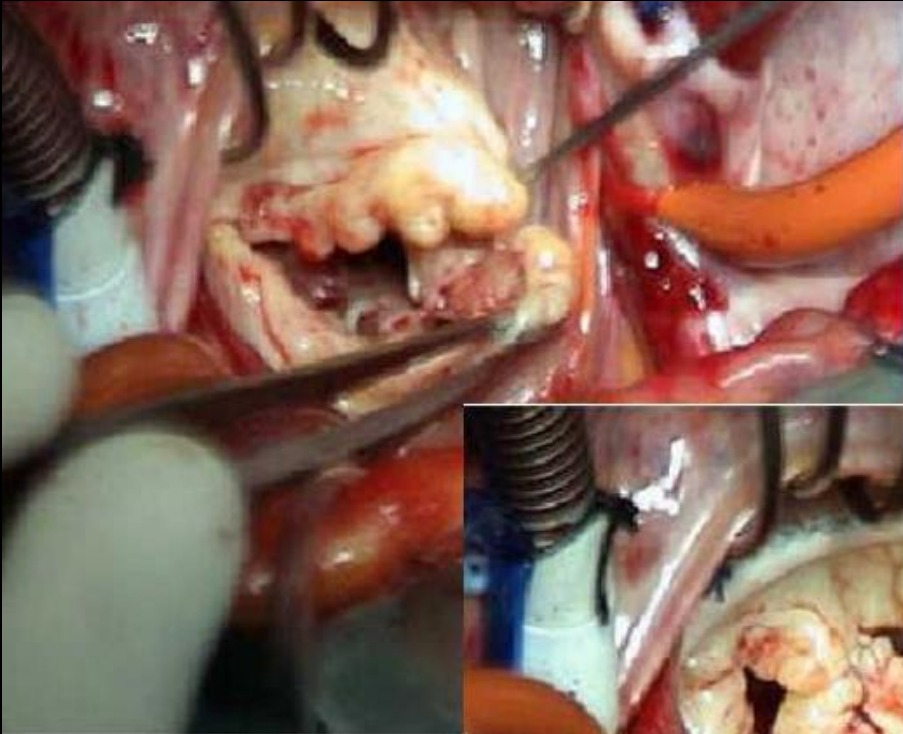
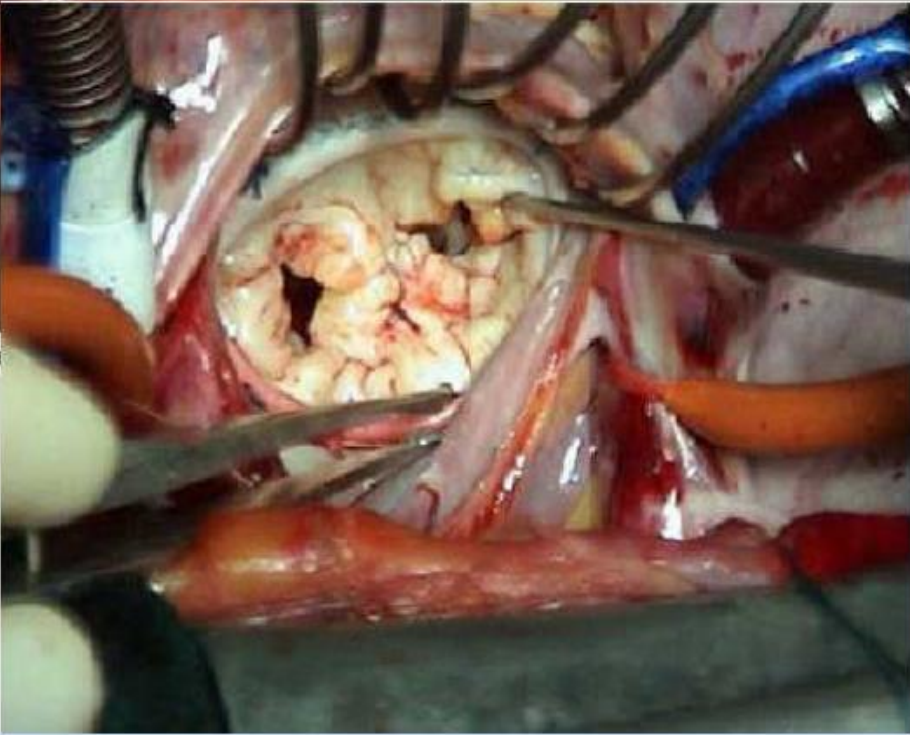
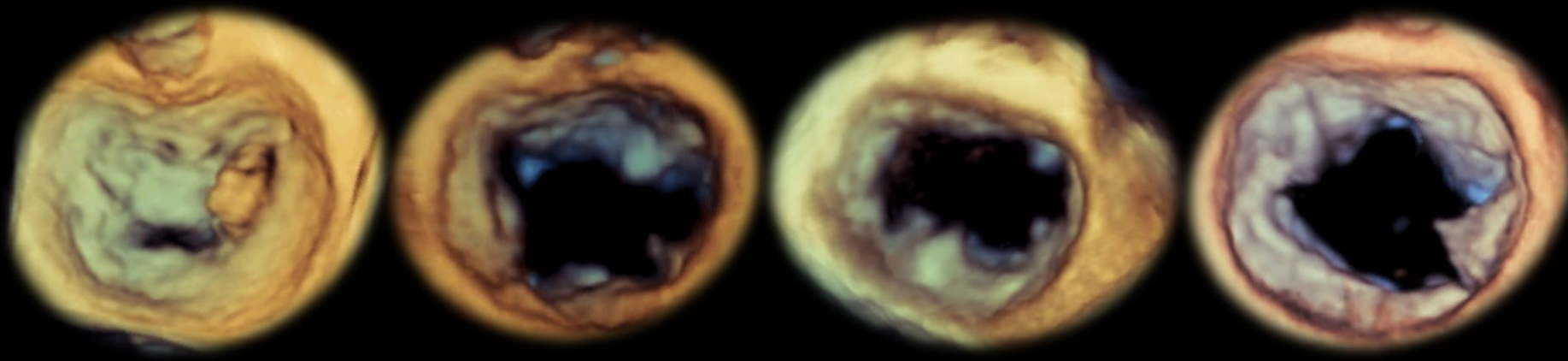
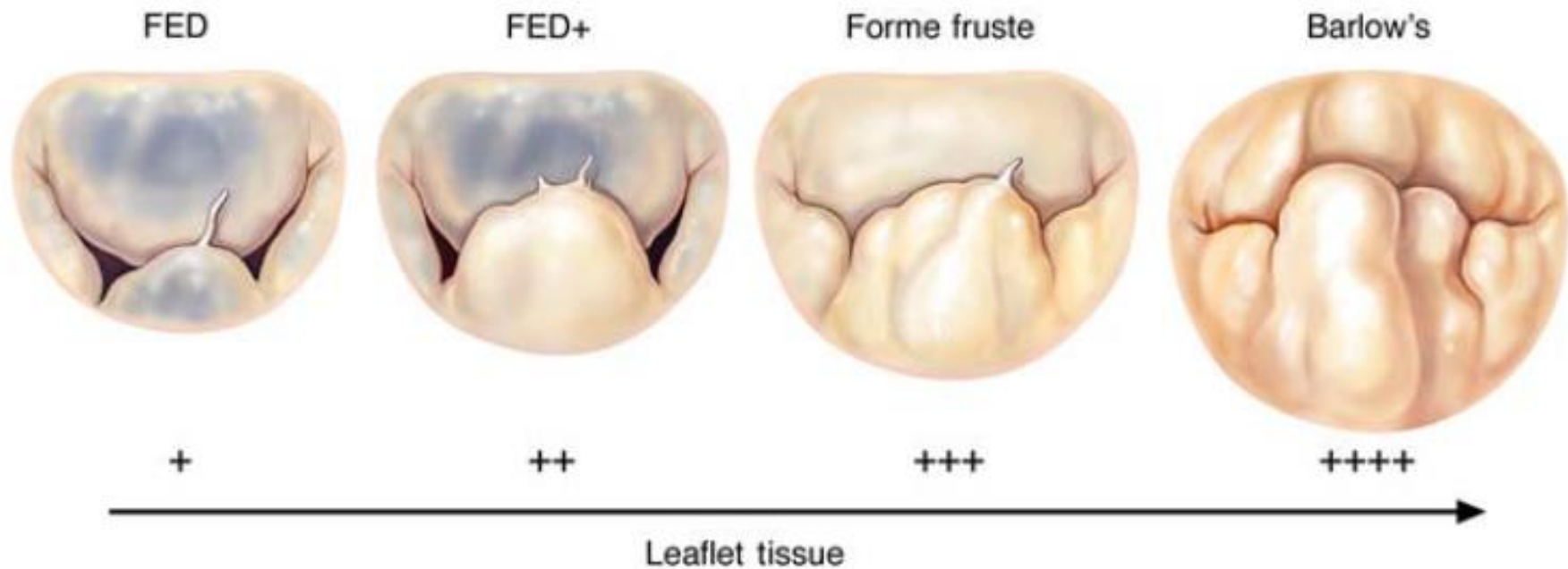


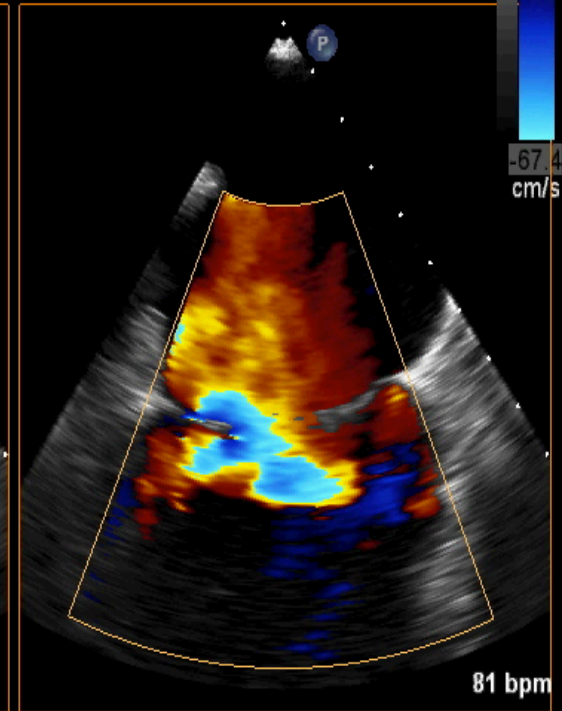
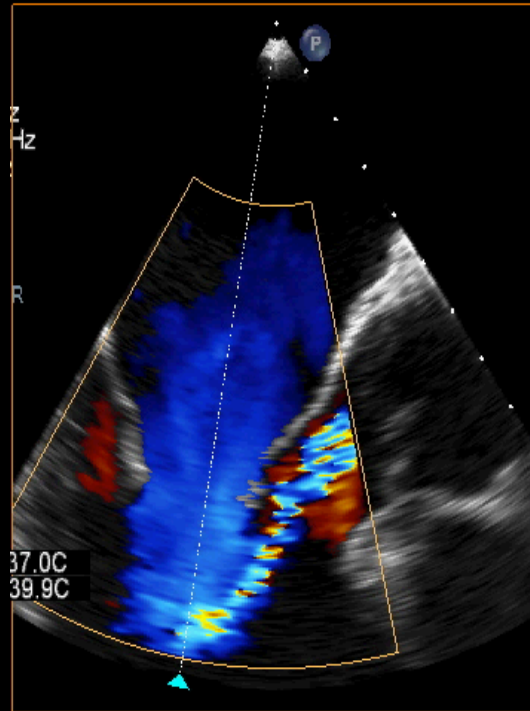
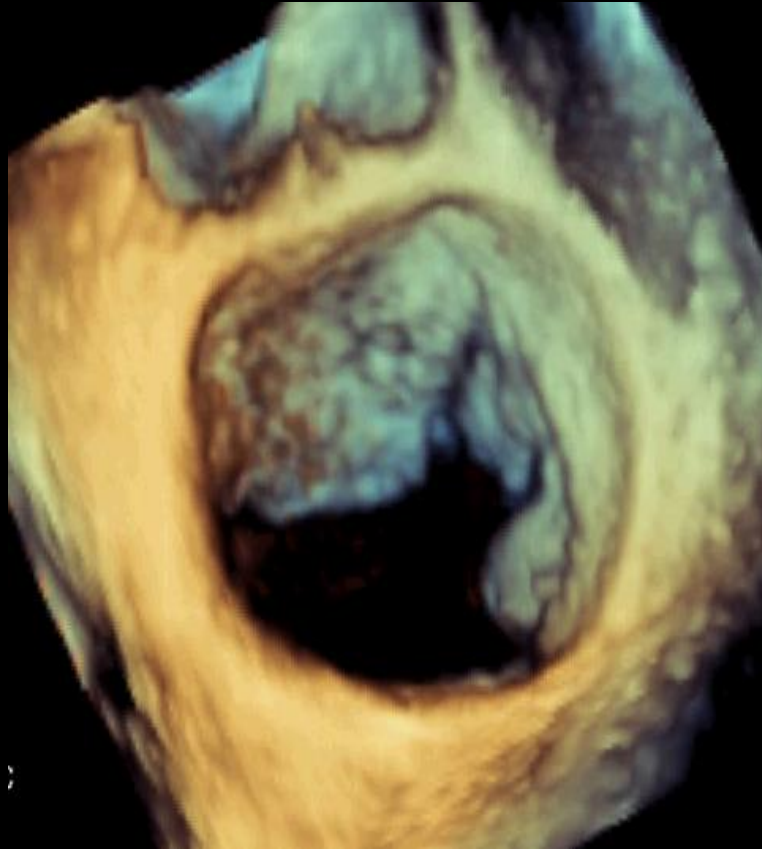
Figure 2: Intraoperative view of a mitral



Degenerative mitral valve regurgitation



Prolasso mitralico complesso

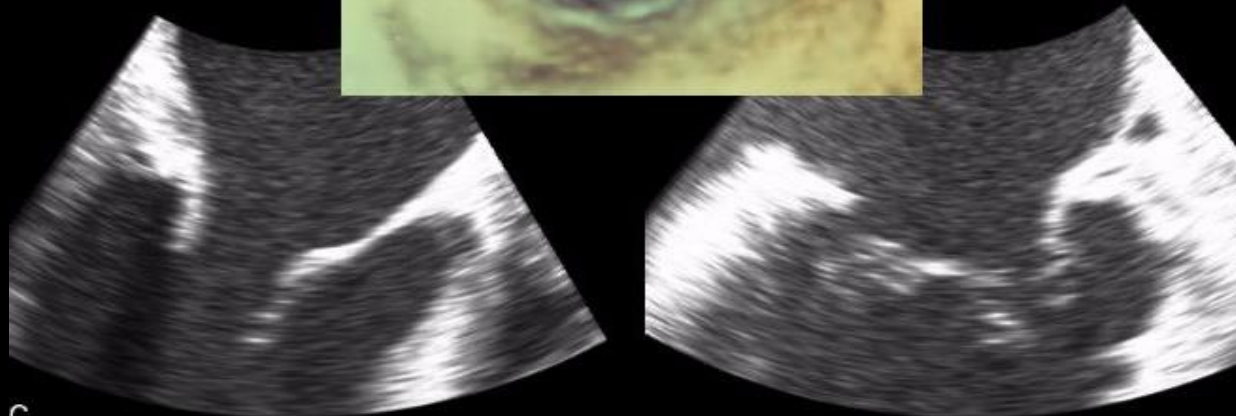


Insufficienza mitralica : funzionale

i

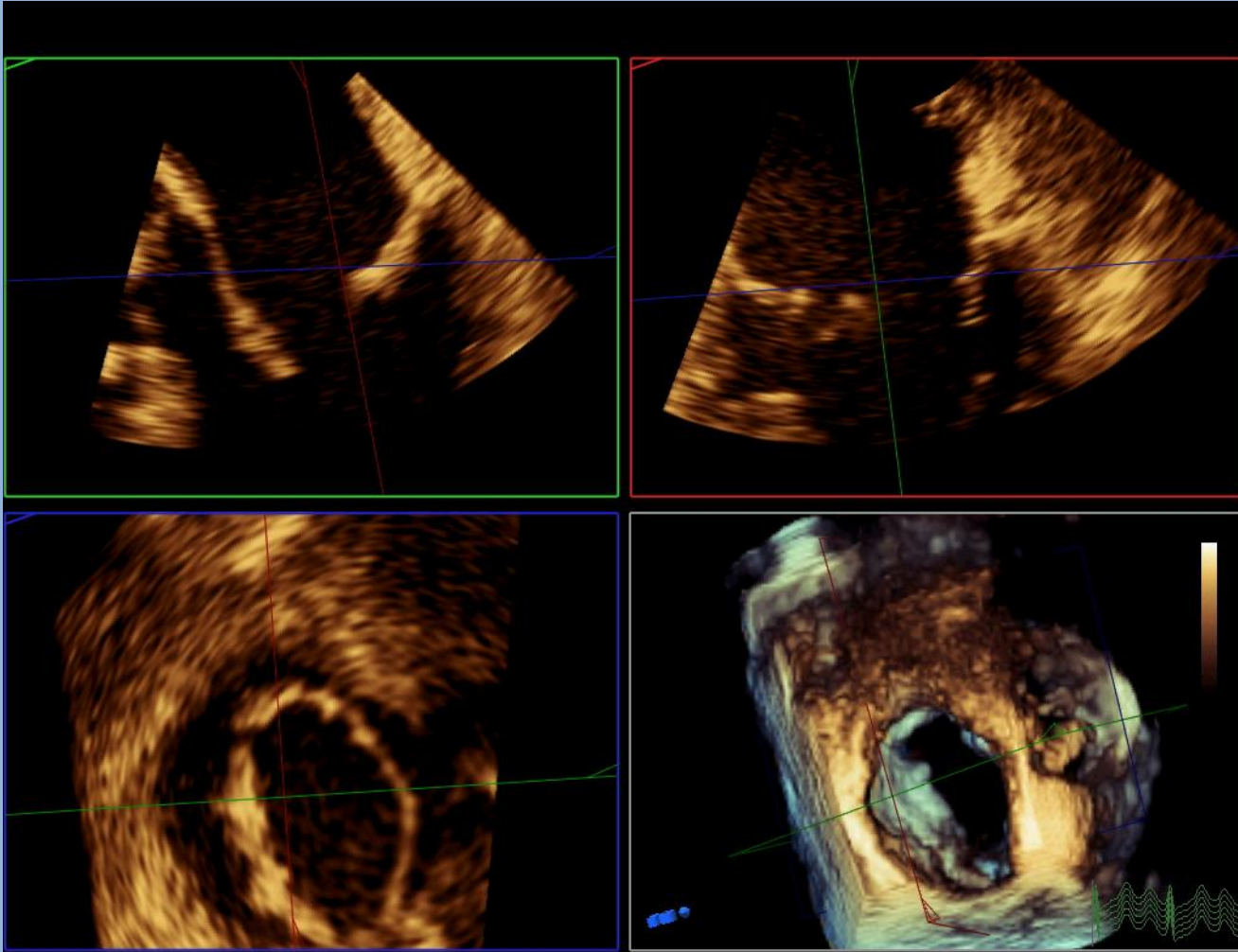
Battiti 3D 1

TIS0.1 MI 0



c

ENDOCARDITE



Eco adulti
X7-2t
45Hz
10cm

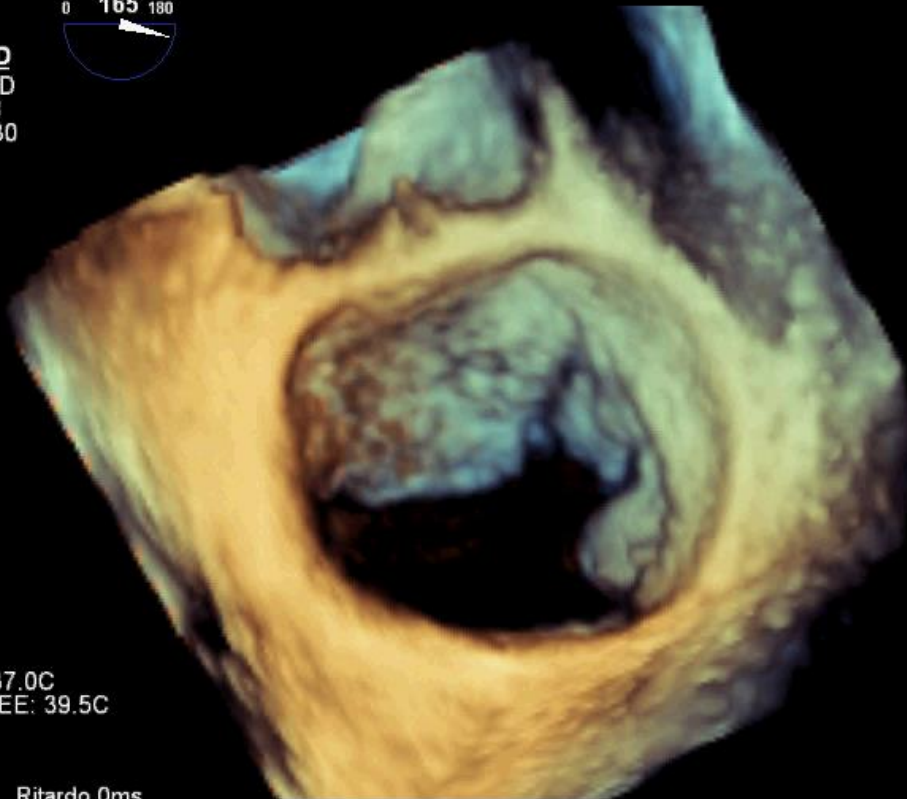
Zoom 3D
2D / 3D
% 58 / 8
C 46 / 30
Gen.



Battiti 3D 6

TIS0.1 MI 0.3

M4



PAT T: 37.0C
Temp. TEE: 39.5C



Ritardo 0ms

79 bpm

Eco adulti
X7-2t
45Hz
10cm

Zoom 3D
2D / 3D
% 58 / 8
C 46 / 30
Gen.

Battiti 3D 6



TIS0.1 MI 0.3

M4



PAT T: 37.0C
Temp. TEE: 39.5C

Ritardo 0ms

79 bpm

LESIONE CALCIFICA ANULUS MITRALICO

Eco adulti
X7-2t
30Hz
8.0cm

Zoom 3D
2D / 3D
% 61 / 17
C 50 / 18
Gen.



Battiti 3D 6

TIS0.1 MI 0.4

M4



PAT T: 37.0C
TEE T: 39.0C



Ritardo 0ms

58 bpm

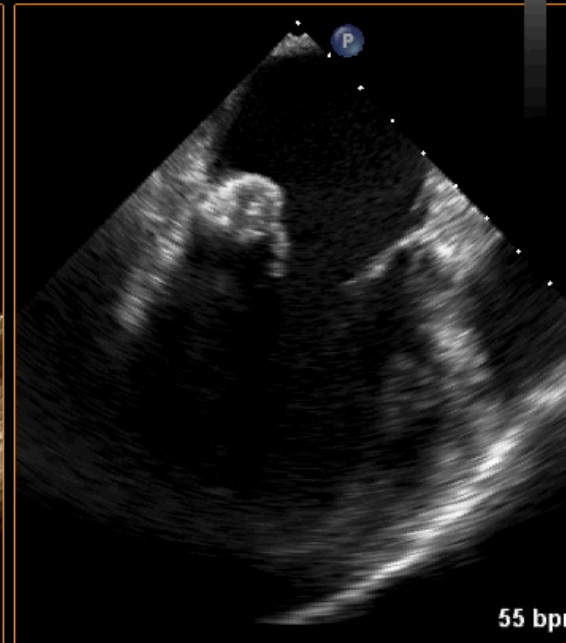
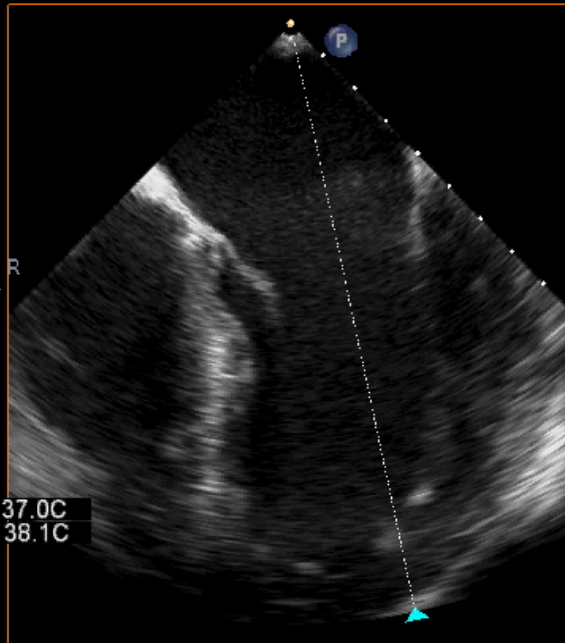
LESIONE CALCIFICA ANULUS MITRALICO

Eco adulti
X7-2t
48Hz
13cm

xPlane
62%
62%
50dB
P Off
Gen.

TIS0.1 MI 0.5

M4



PAT T: 37.0C
TEE T: 38.1C

!

55 bpm

M. DI BARLOW

Eco adulti
X7-2t
41Hz
7.5cm

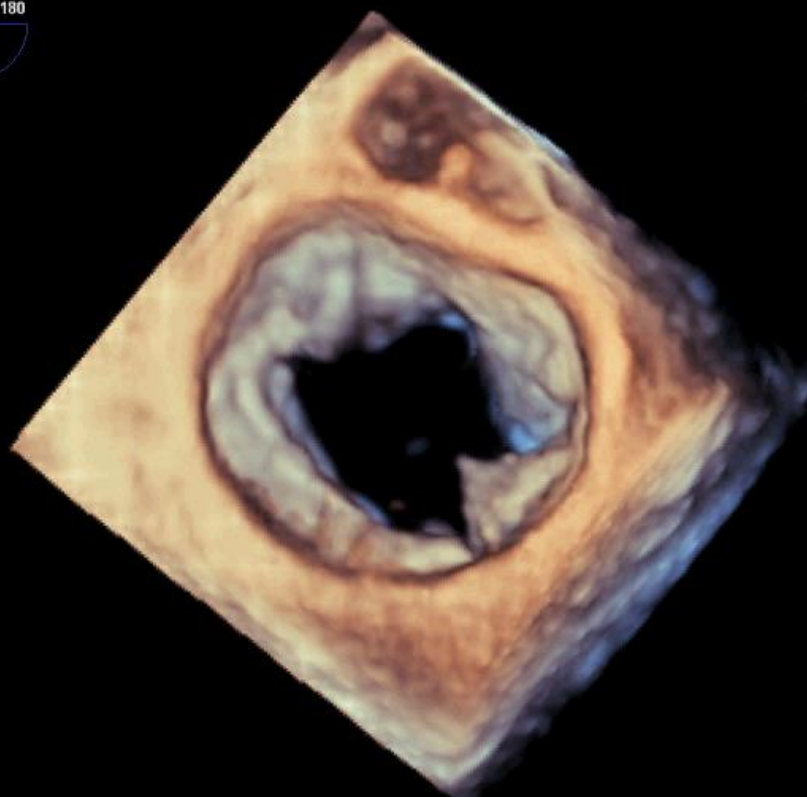
Zoom 3D
2D / 3D
% 60 / 12
C 48 / 30
Pen.



Battiti 3D 6

HR: 62
TISO.1 MI 0.3

M4



PAT T: 37.0C
TEE T: 39.9C

JPEG

Ritardo 0ms

62 bpm

21/05/2015 11:59

M. DI BARLOW

Eco adulti
X7-2t
36Hz
8.3cm

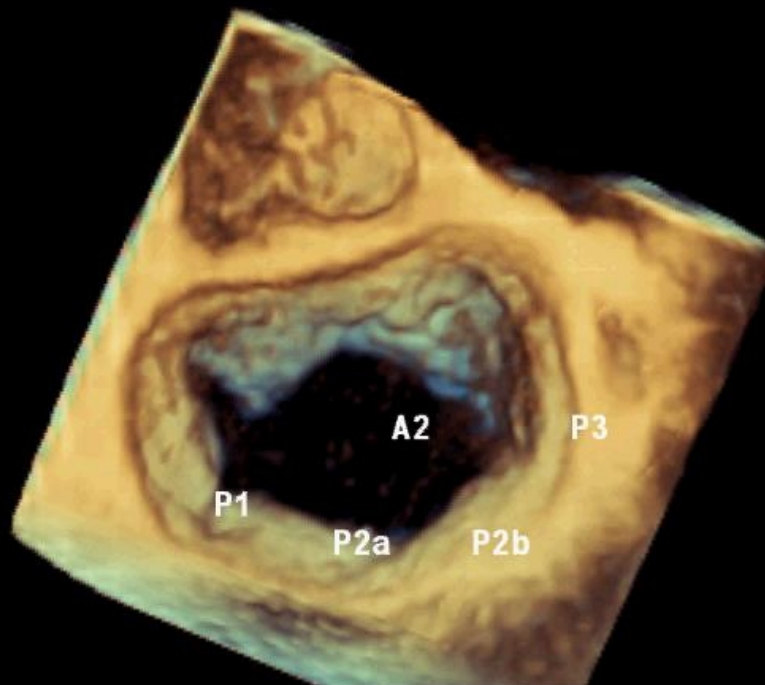
Zoom 3D
2D / 3D
% 69 / 0
C 41 / 32
Gen.



Battiti 3D 6

TIS0.1 MI 0.3

M4



PAT T: 37.0C
Temp. TEE: 40.1C

Ritardo 0ms

72 bpm

FLAIL

Eco adulti
X7-2t
24Hz
7.0cm

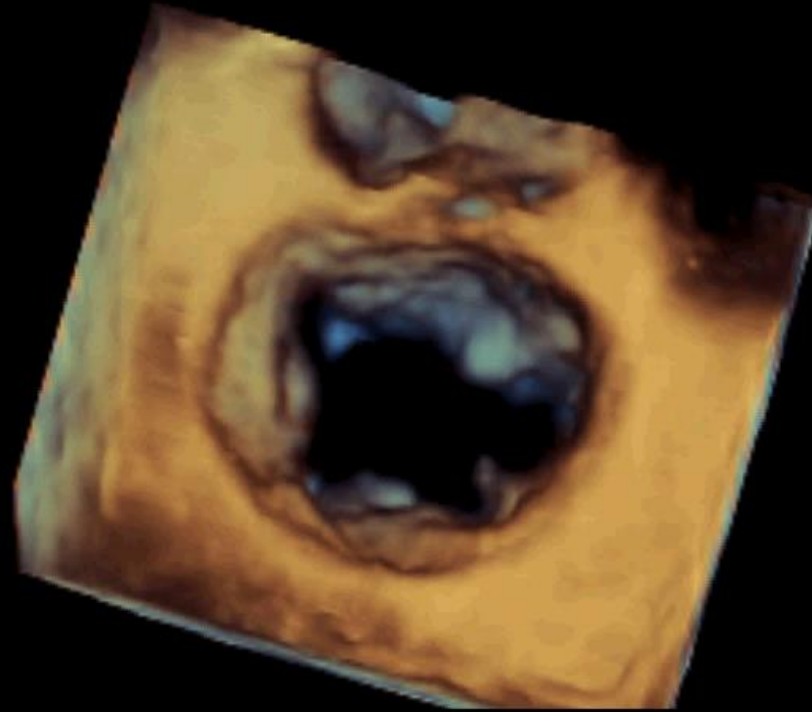
Zoom 3D
2D / 3D
% 60 / 0
C 44 / 30
Gen.



Battiti 3D 1

TIS0.1 MI 0.3

M4



PAT T: 37.0C
TEE T: 37.1C



96 bpm

FLAIL

Eco adulti
X7-2t
53Hz
13cm

2D
79%
C 36
P Off
Gen.



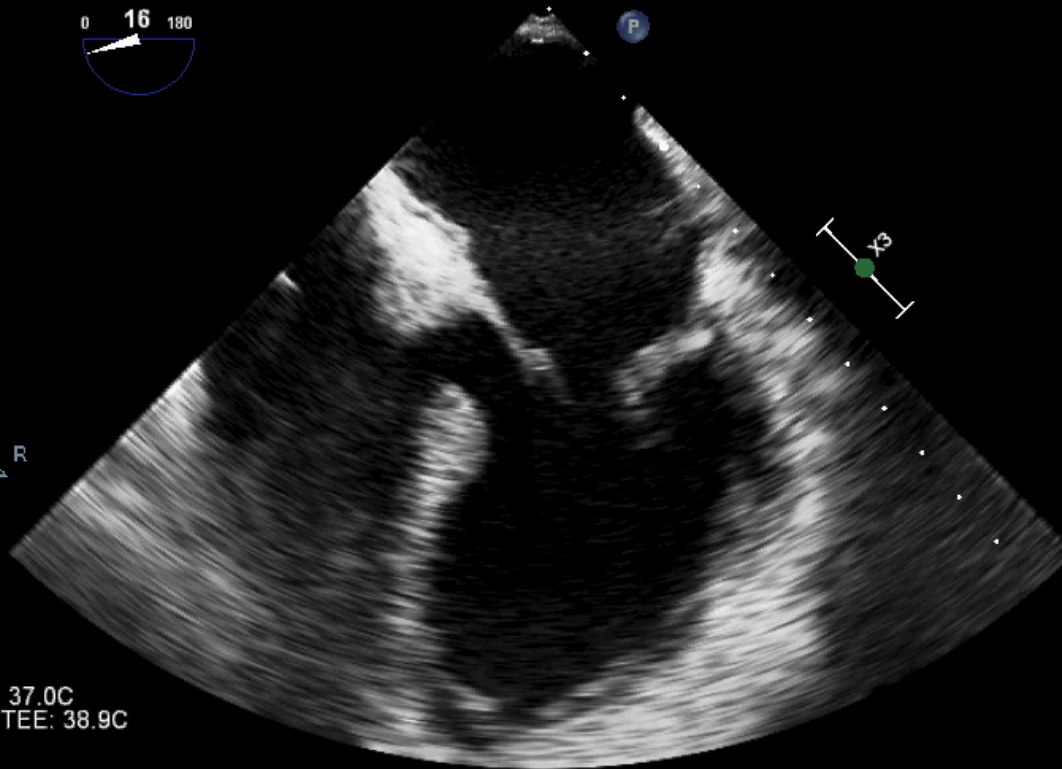
TISO.0 MI 0.1

M4



PAT T: 37.0C
Temp. TEE: 38.9C

65 bpm



FLAIL

Eco adulti
X7-2t
53Hz
13cm

2D
79%
C 36
P Off
Gen.



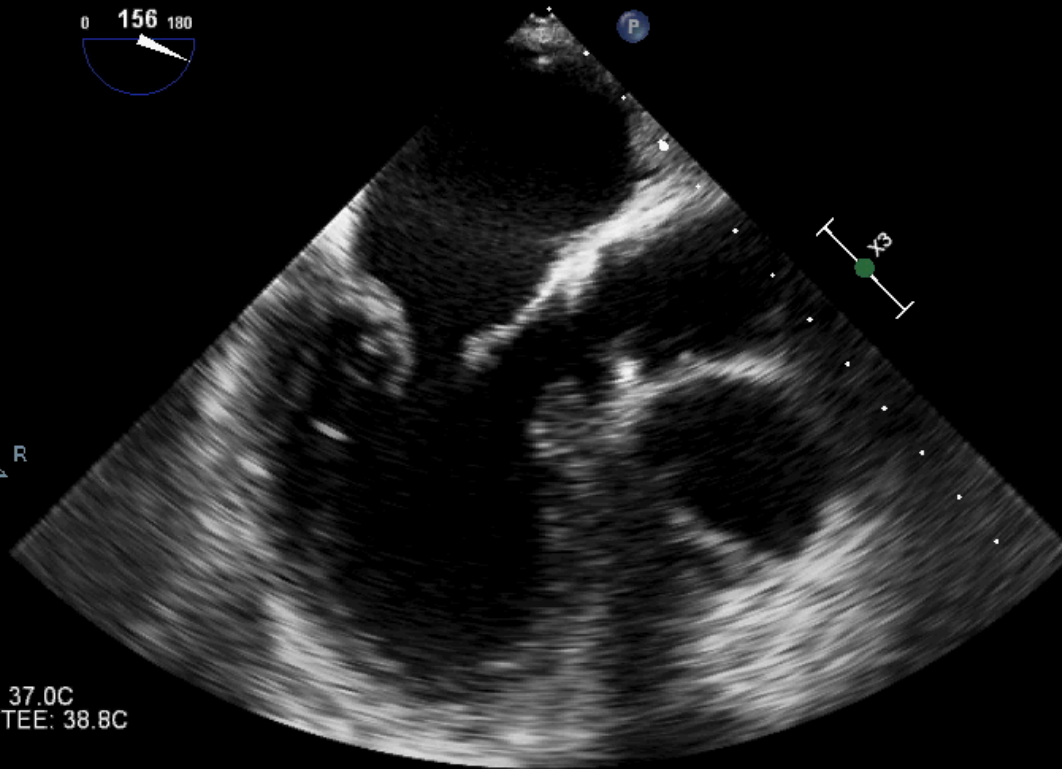
TIS0.0 MI 0.1

M4



PAT T: 37.0C
Temp. TEE: 38.8C

52 bpm



PROLASSO PARACOMMISSURALE

TEEintraoper
X7-2t
61Hz
11cm

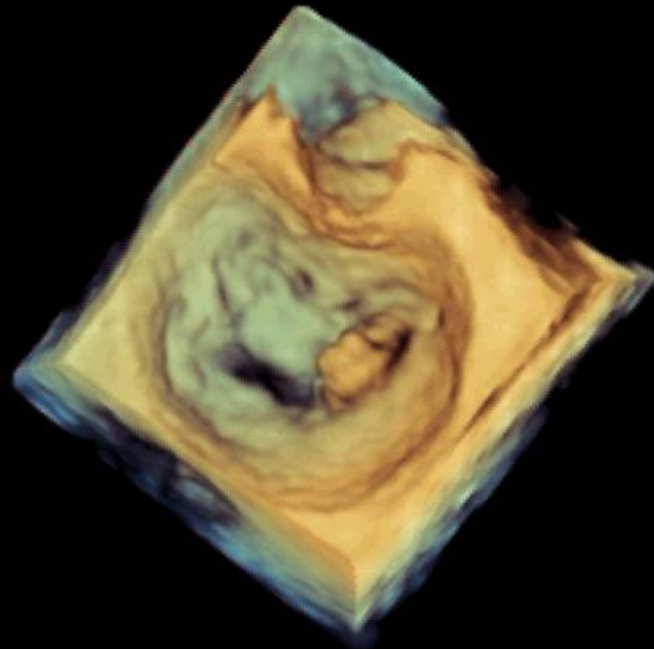
Zoom 3D
2D / 3D
% 75 / 0
C 38 / 30
Gen.



Battiti 3D 6

TIS0.0 MI 0.2

M4



PAT T: 37.0C
TEE T: 37.6C

Ritardo 0ms

57 bpm

TETHERING

Eco adulti
X7-2t
50Hz
9.1cm

Battiti 3D 1

TIS0.1 MI 0.3

M4

Zoom 3D
2D / 3D
% 58 / 0
C 46 / 30
Gen.



PAT T: 37.0C
TEE T: 37.2C



82 bpm

PROLASSO + CLEFT

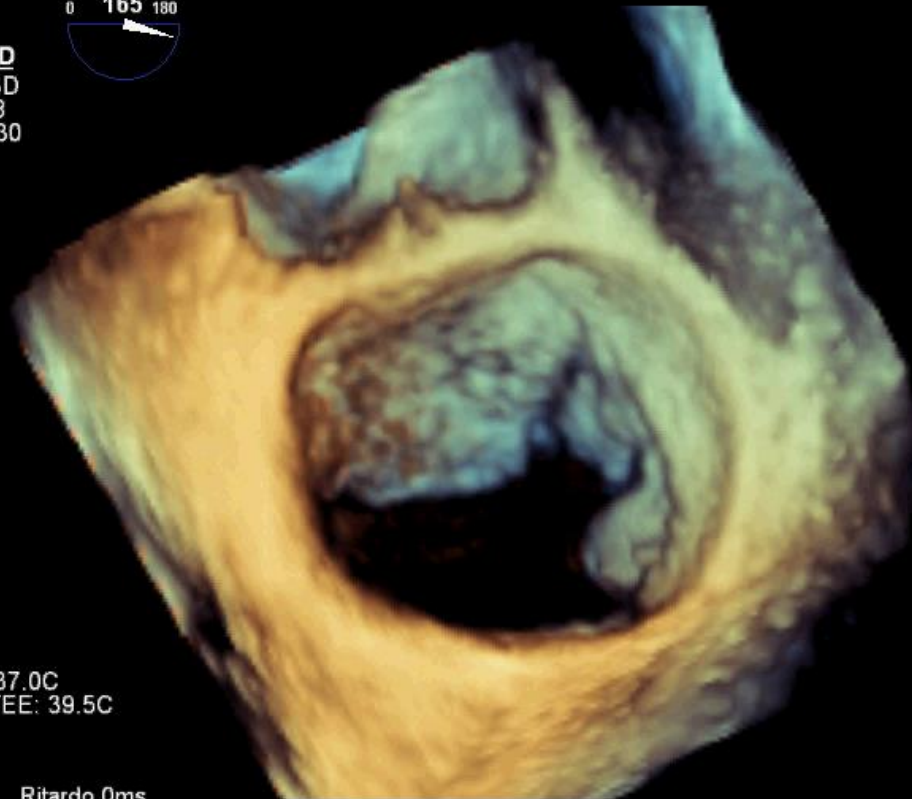
Eco adulti
X7-2t
45Hz
10cm

Zoom 3D
2D / 3D
% 58 / 8
C 46 / 30
Gen.

Battiti 3D 6



TIS 0.1 MI 0.3



PAT T: 37.0C
Temp. TEE: 39.5C

Ritardo 0ms

79 bpm

Tecnica di impianto

ANIMAZIONE



Eco adulti

X7-2t

22Hz

12cm

2D

61%

C 50

P Off

Gen.

CF

48%

6632Hz

WF 596Hz

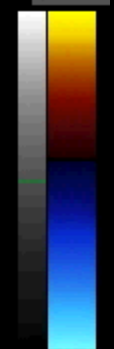
4.4MHz



TIS0.6 MI 0.3

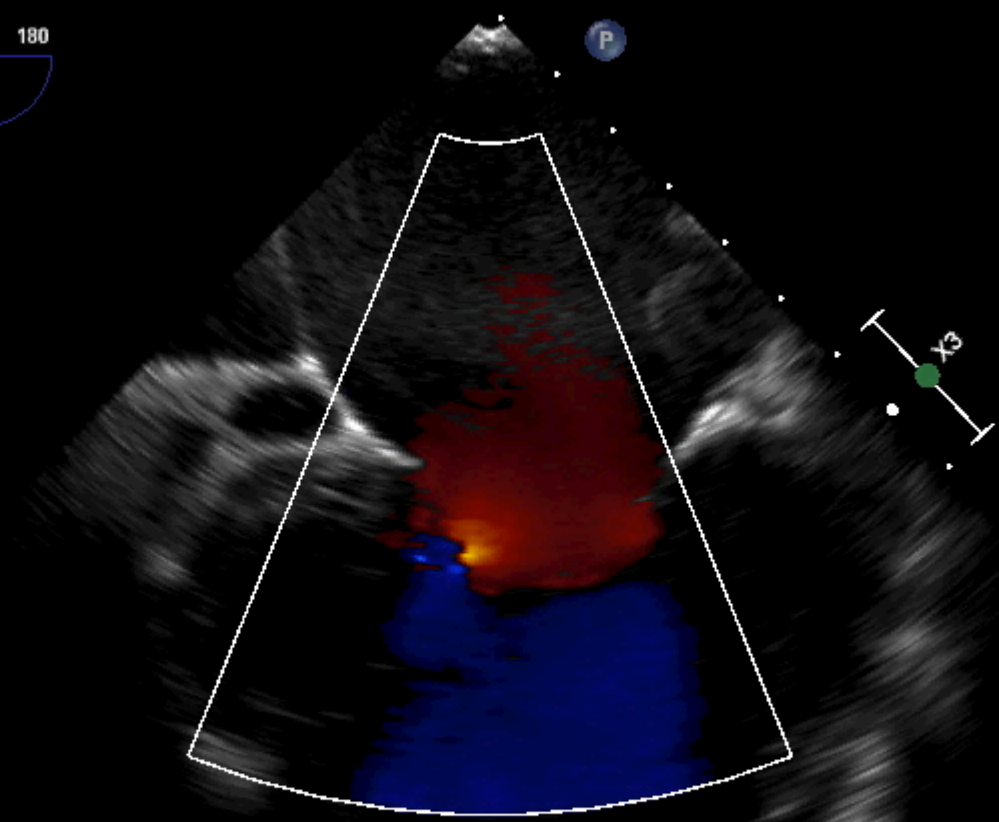
M4 M4

+50.3



-64.7

cm/s



PAT T: 37.0C
TEE T: 38.7C



50 bpm

Eco adulti

X7-2t

76Hz

9.0cm



TISO.2 MI 0.9

2D

56%

C 46

P Off

AGen

M4



PAT T: 37.0C
TEE T: 39.6C

53 bpm

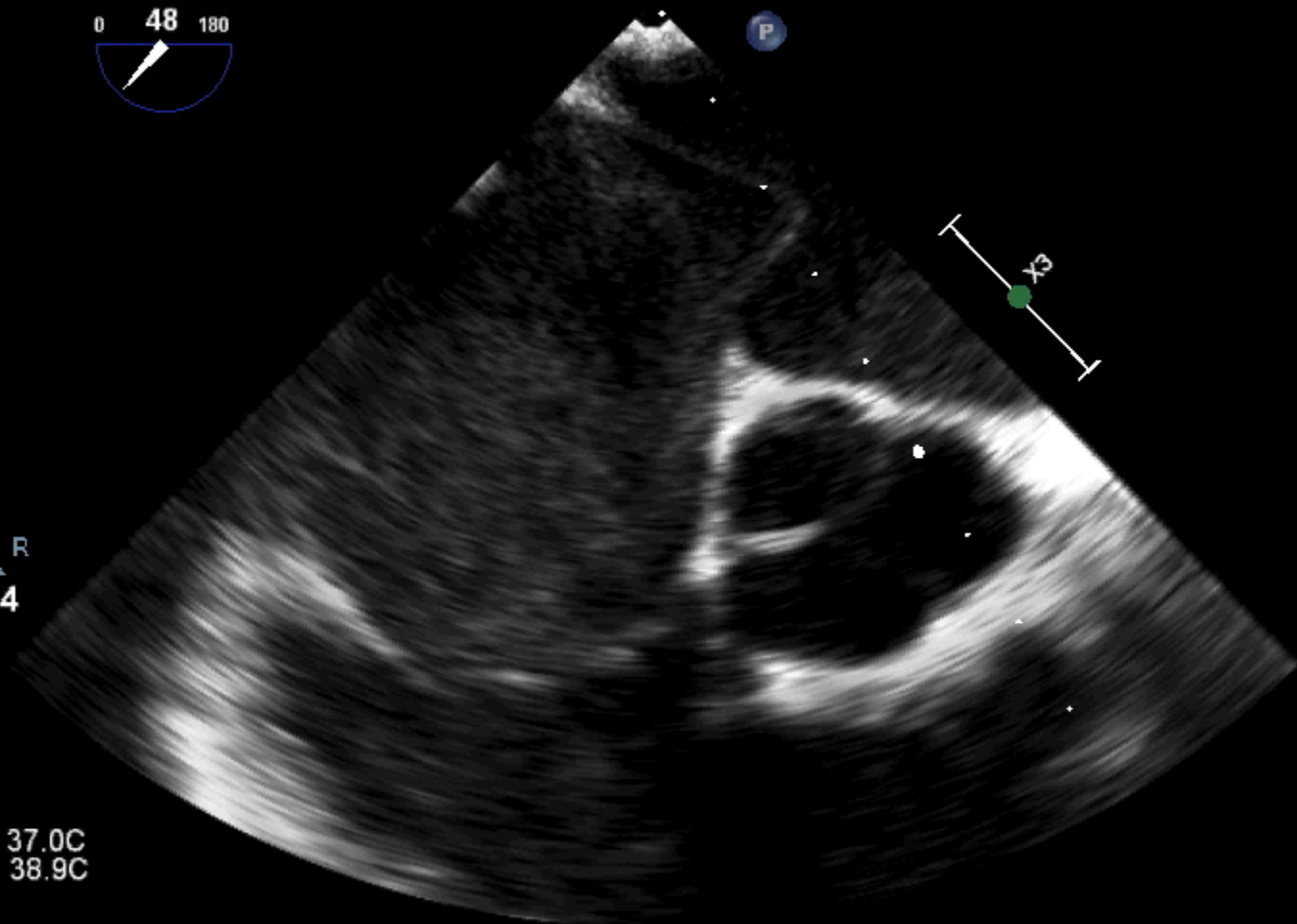
Eco adulti
X7-2t
76Hz
9.0cm

TISO.2 MI 0.9



2D
56%
C 46
P Off
AGen

M4



PAT T: 37.0C
TEE T: 38.9C

50 bpm

Eco adulti

X7-2t

76Hz

9.0cm



TISO.2 MI 0.9

2D

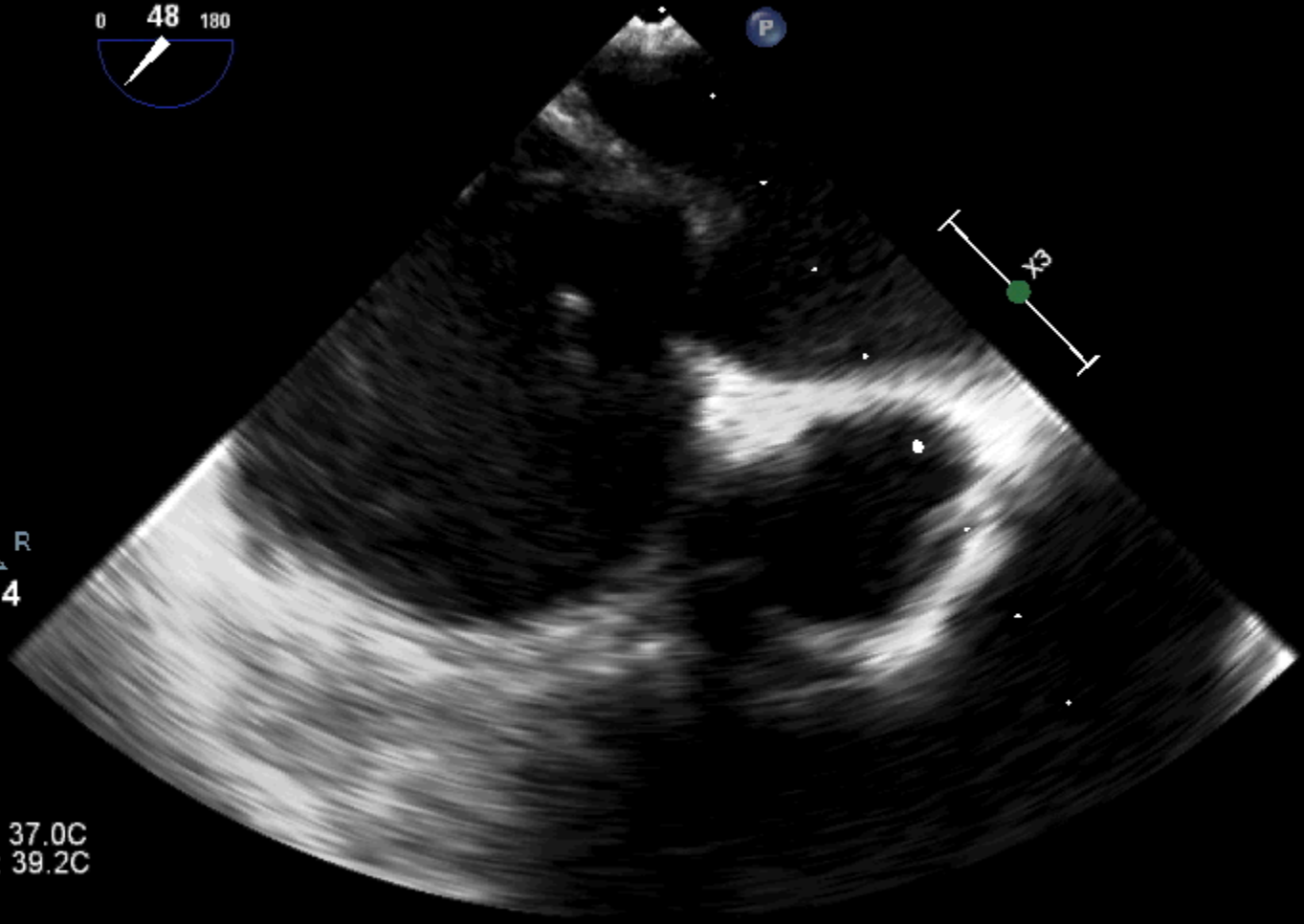
56%

C 46

P Off

AGen

M4

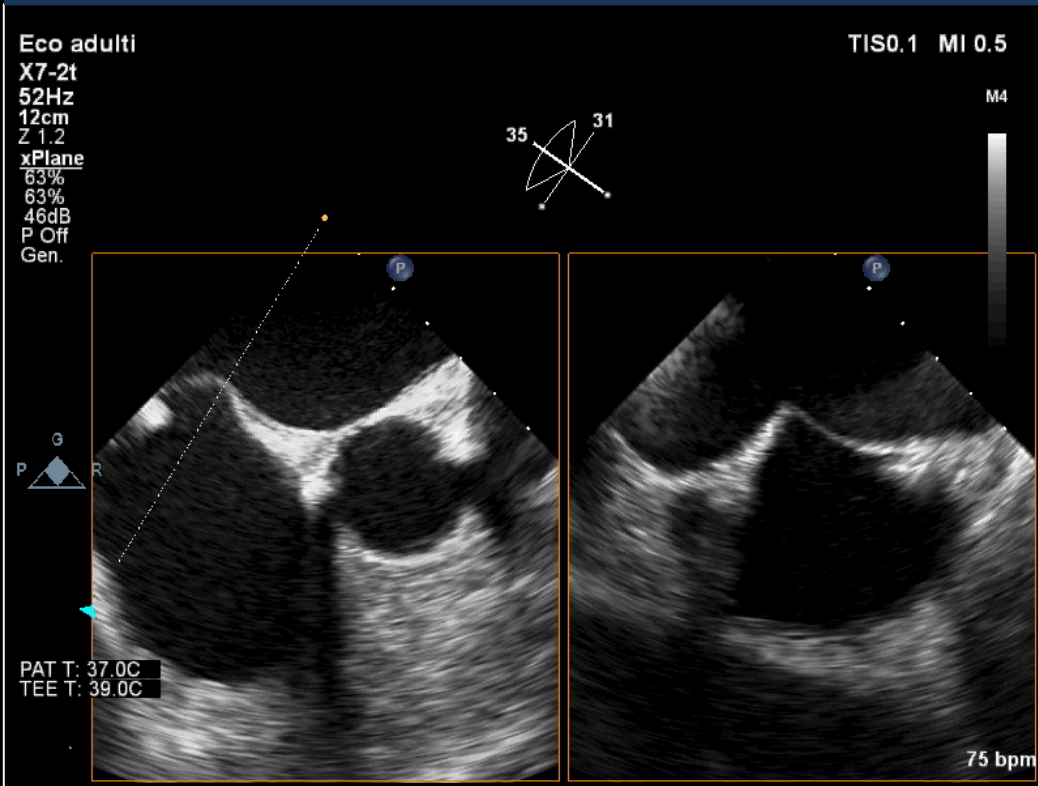


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TEE T: 39.2C

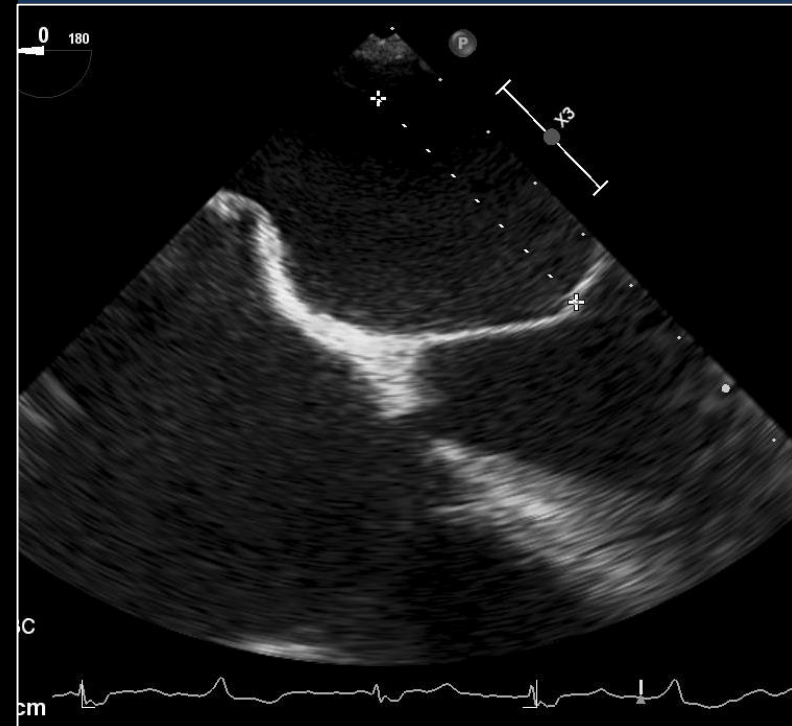
50 bpm

MITRACLIP

PUNTURA SETTALE



DISTANZA PUNTURA SETTALE / COAPTAZIONE MITRALE



Eco adulti

X7-2t

52Hz

12cm

Z 1.2

xPlane

63%

63%

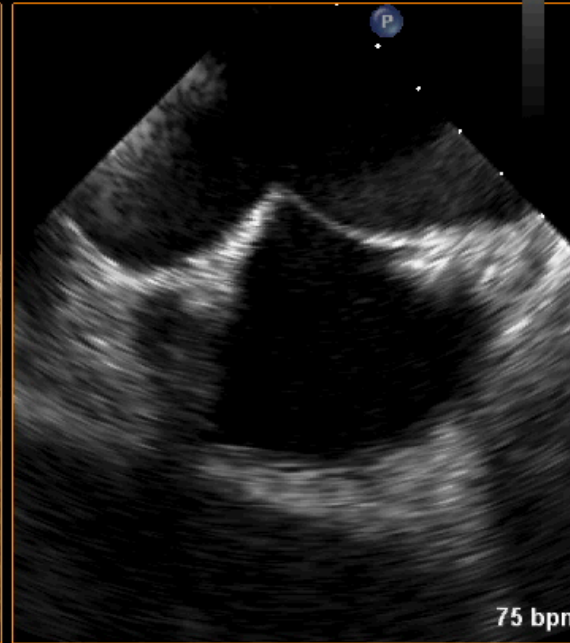
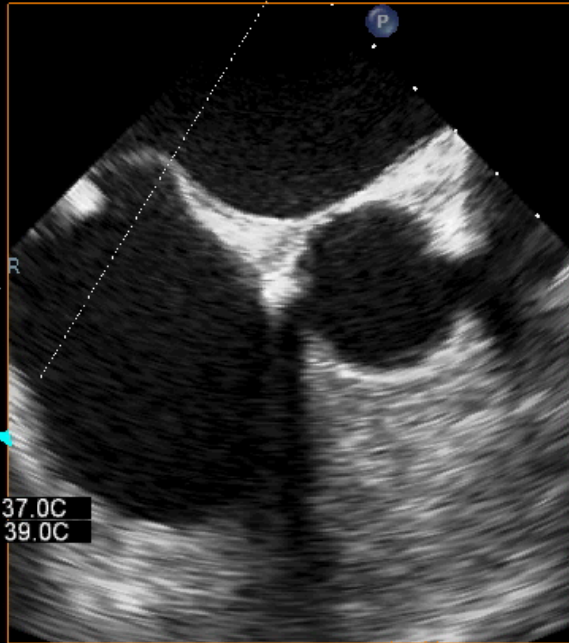
46dB

P Off

Gen.

TISO.1 MI 0.5

M4



PAT T: 37.0C
TEE T: 39.0C

75 bpm

Eco adulti

X7-2t

37Hz

9.0cm



TISO.0 MI 0.1

2D

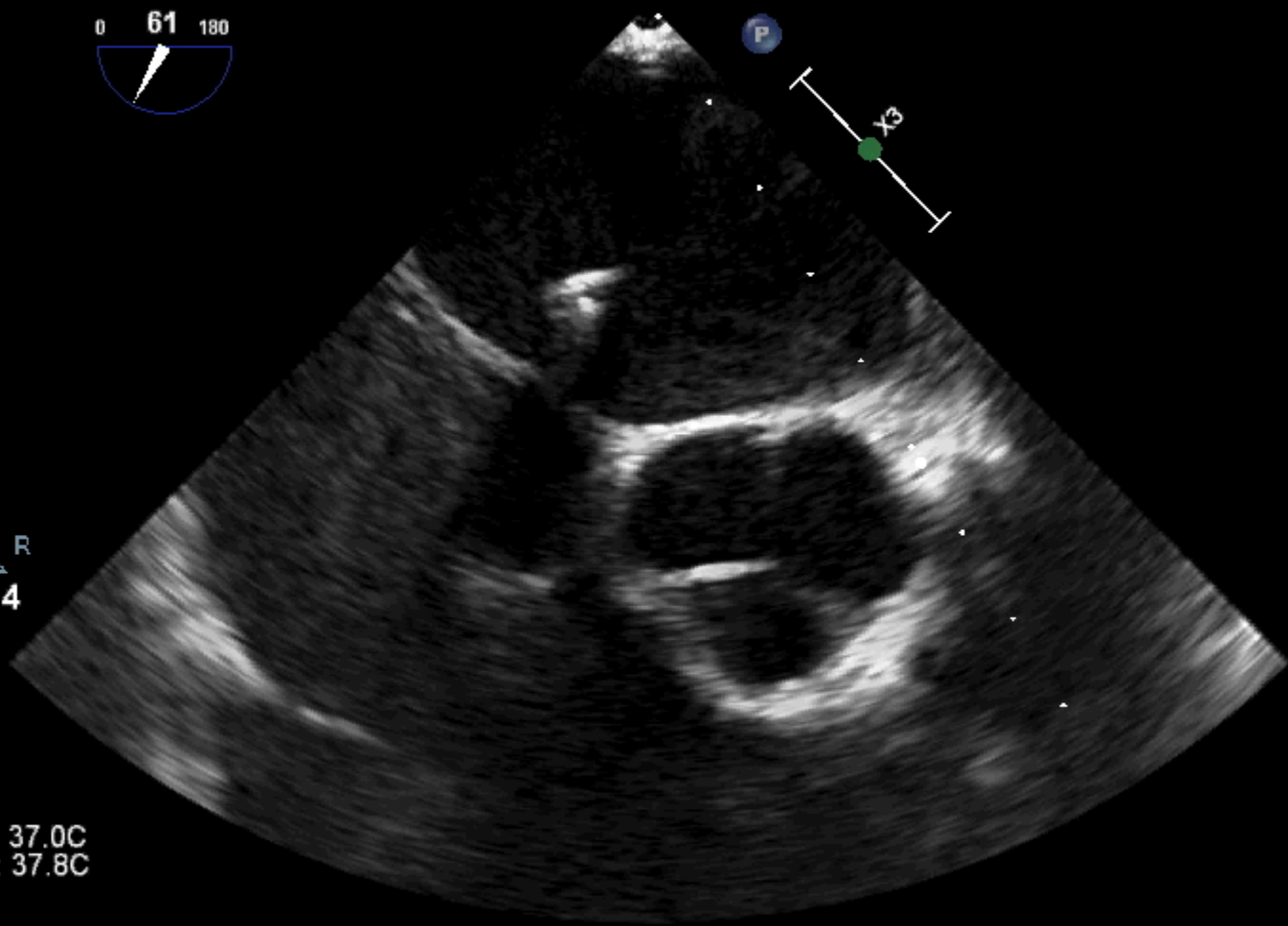
64%

C 51

P Off

AGen

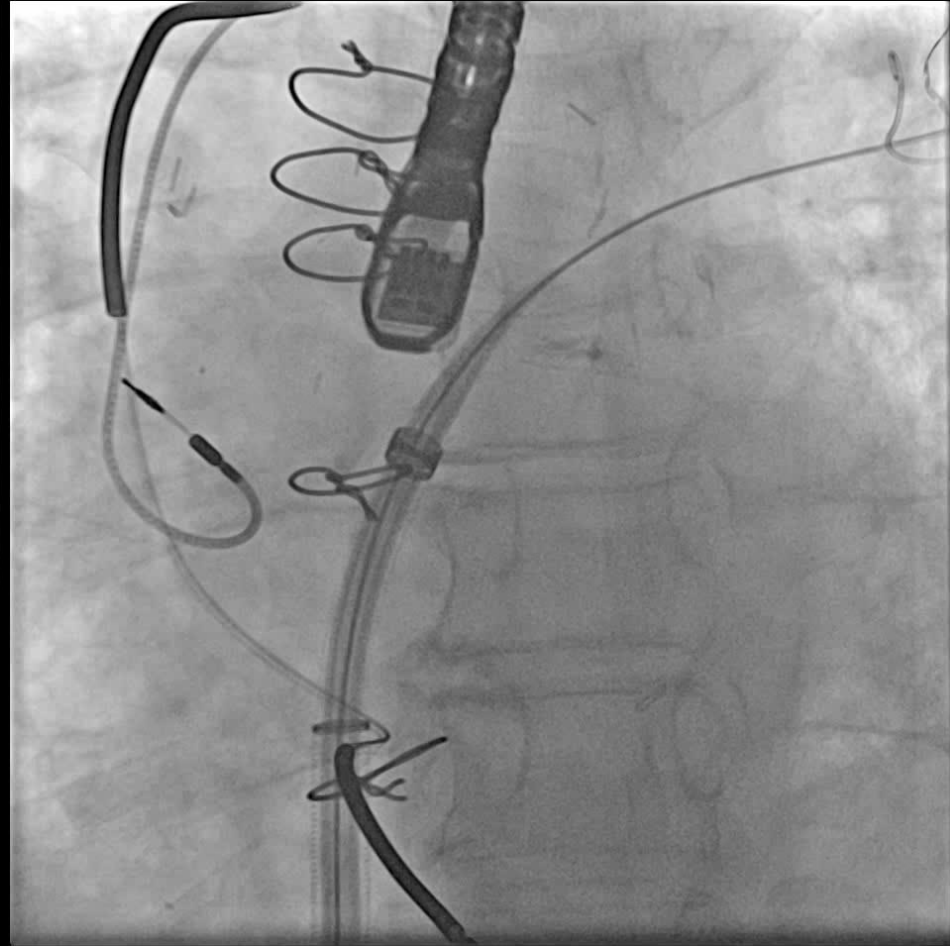
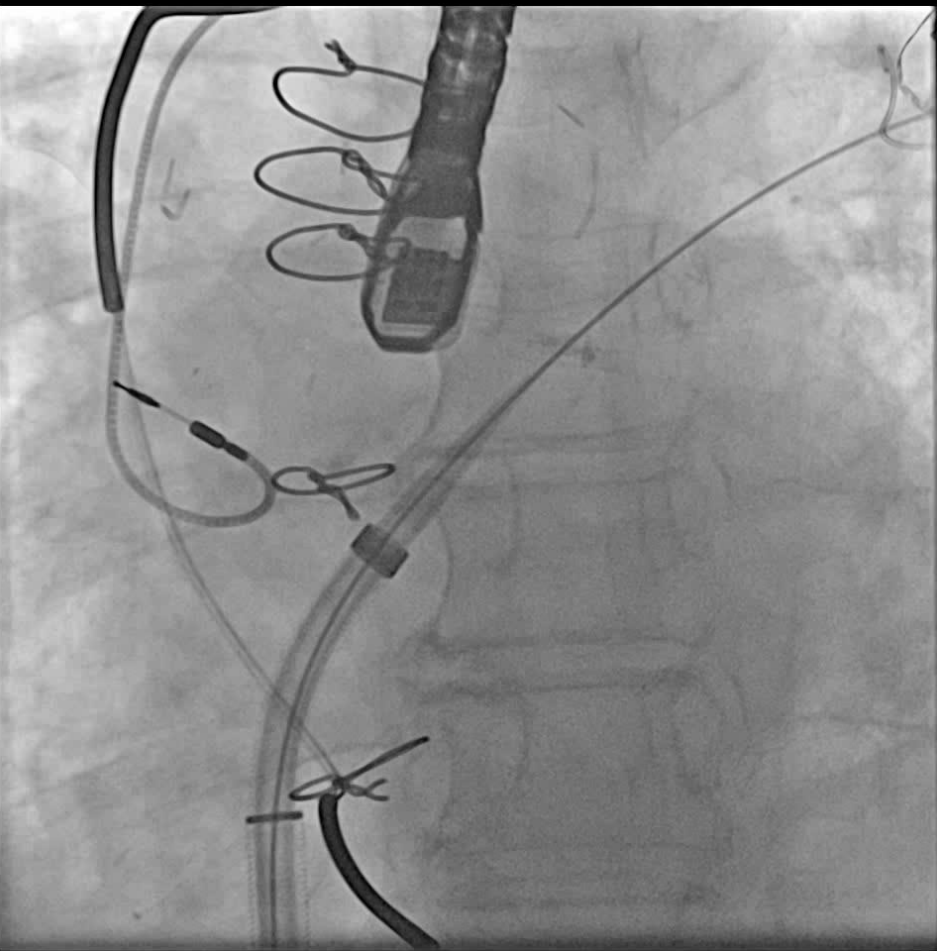
M4

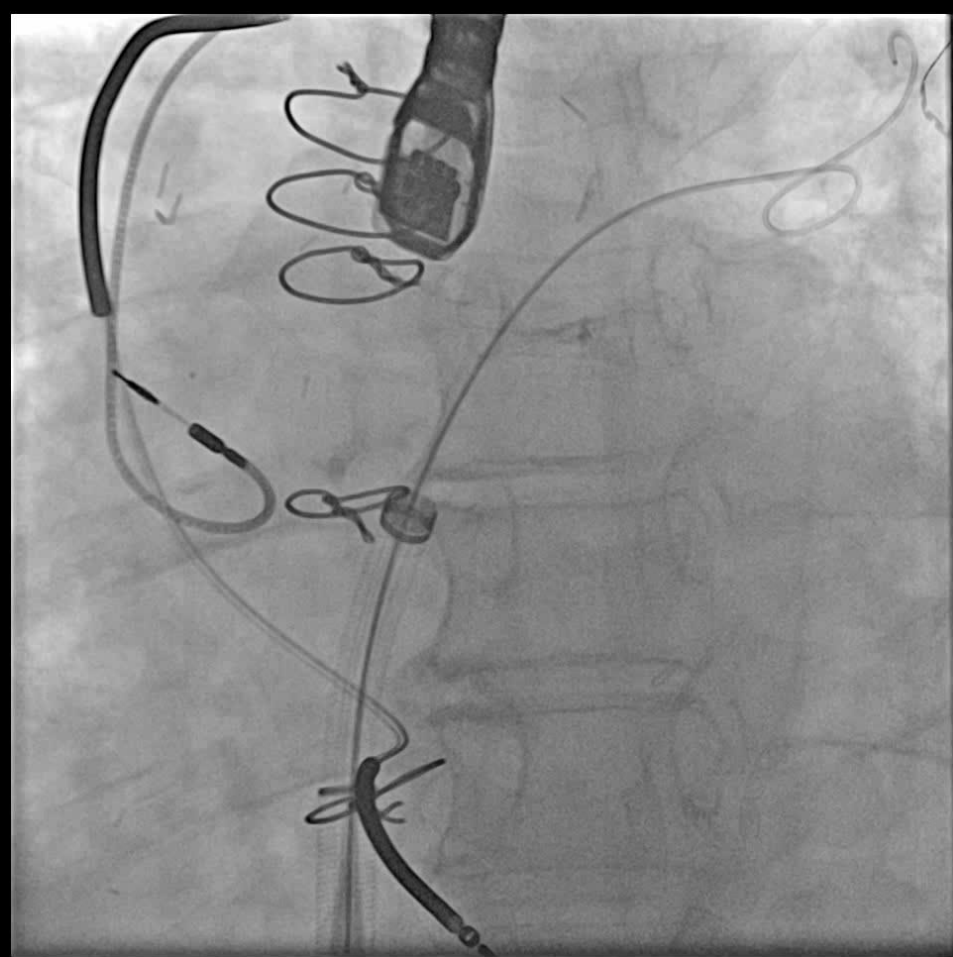


PAT T: 37.0C
TEE T: 37.8C

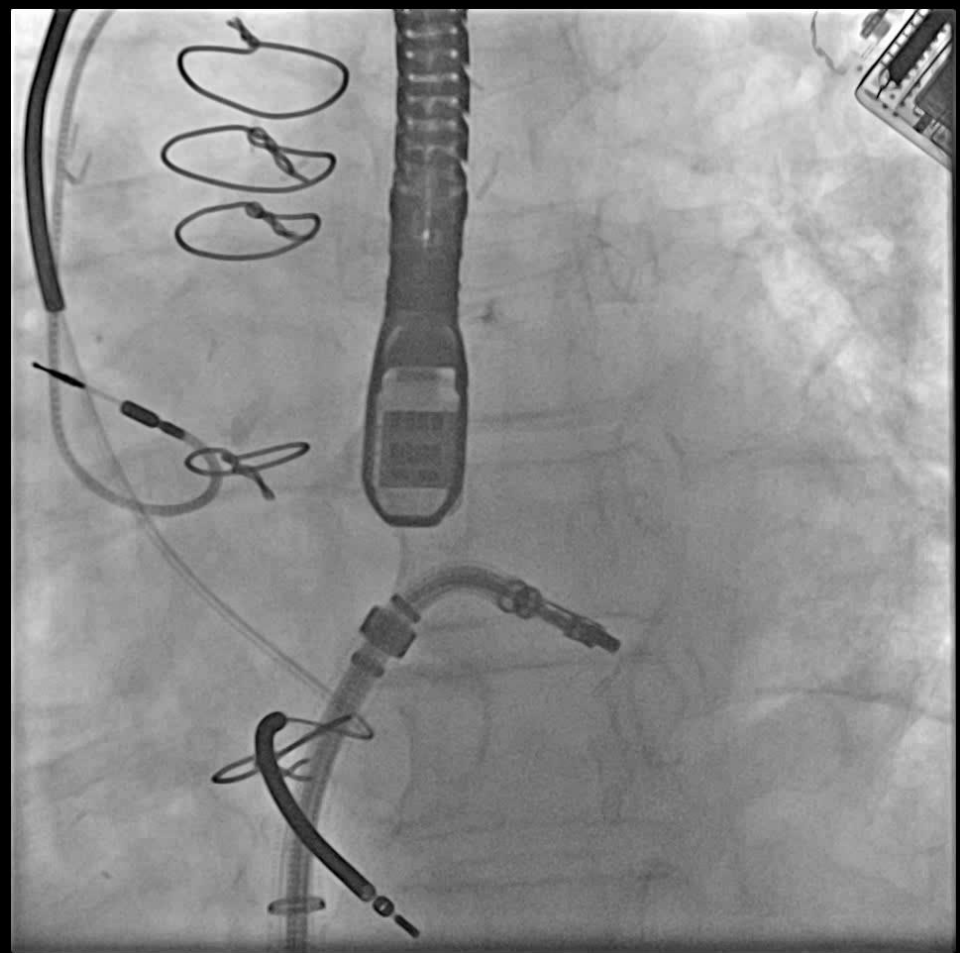
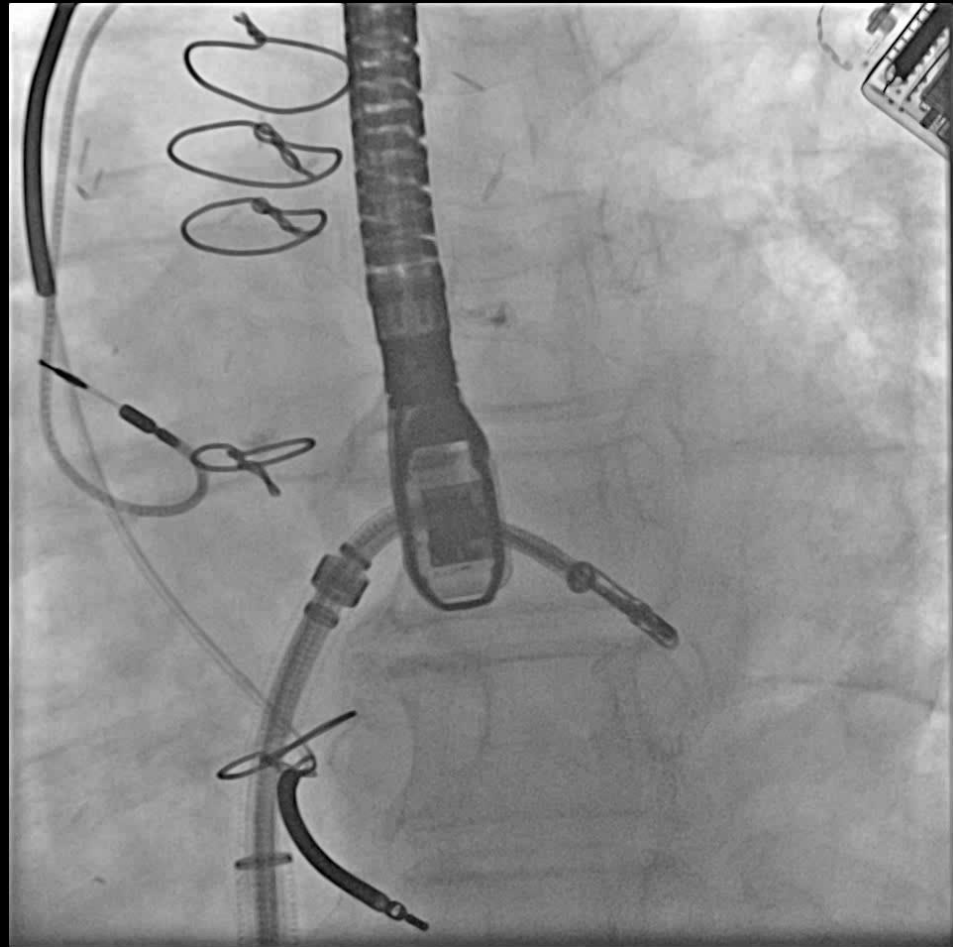
!

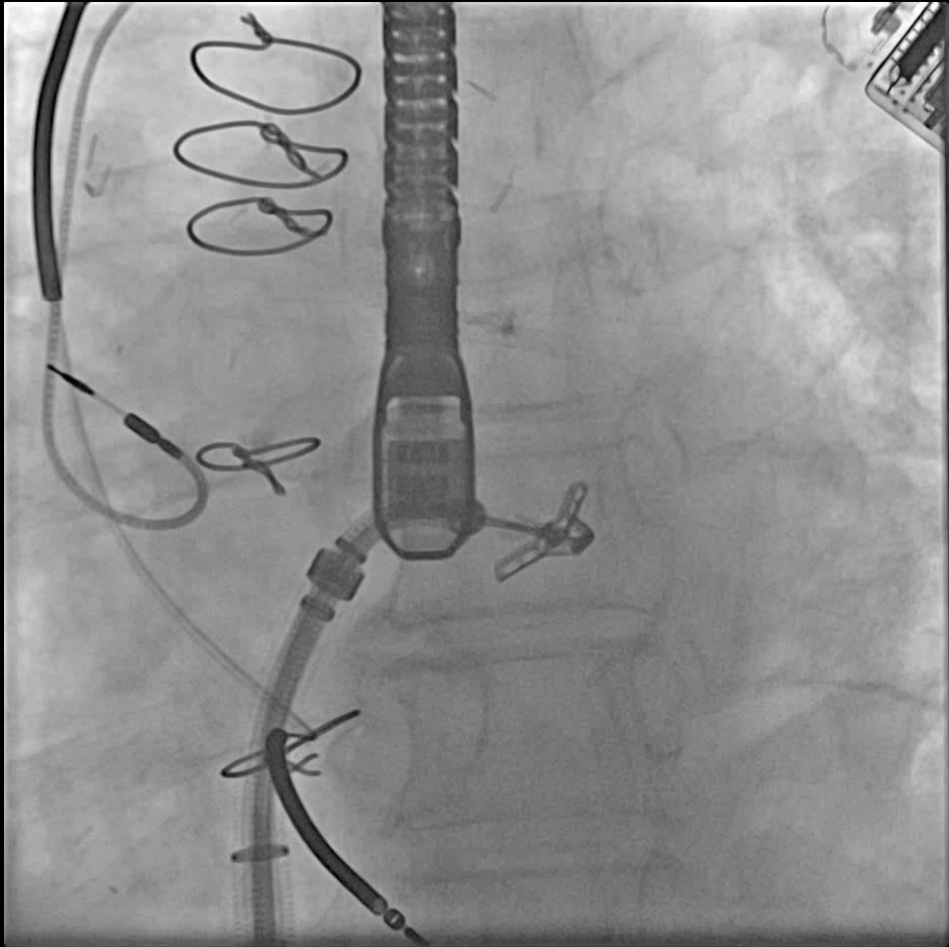
50 bpm











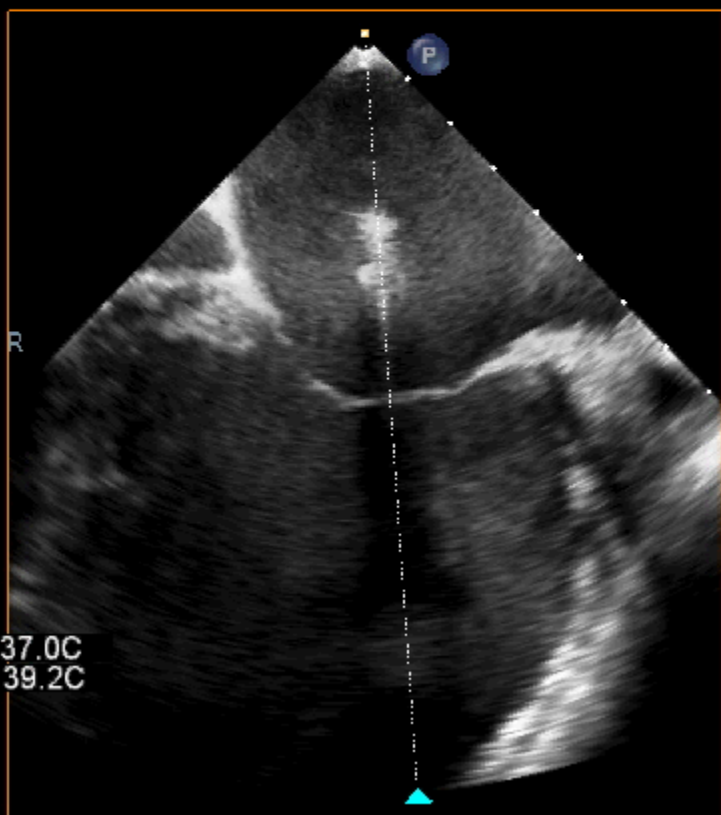
Eco adulti
X7-2t
52Hz
12cm

TISO.1 MI 0.2

xPlane
71%
71%
40dB
P Alto
Gen.



M4



PAT T: 37.0C
TEE T: 39.2C

Eco adulti

X7-2t

52Hz

12cm

xPlane

69%

69%

40dB

P Alto

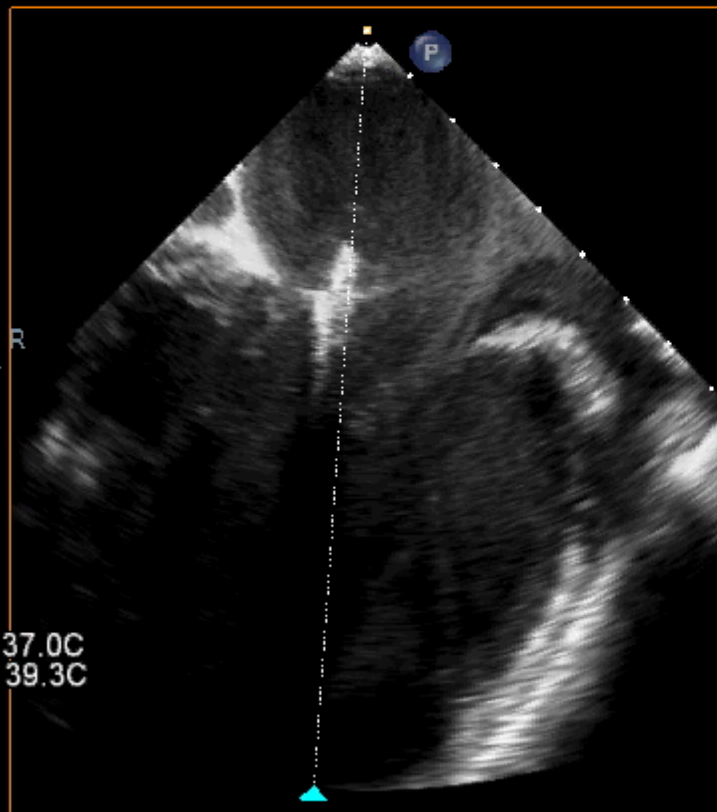
Gen.

TIS0.1 MI 0.2

M4

80

4



PAT T: 37.0C
TEE T: 39.3C

50 bpm

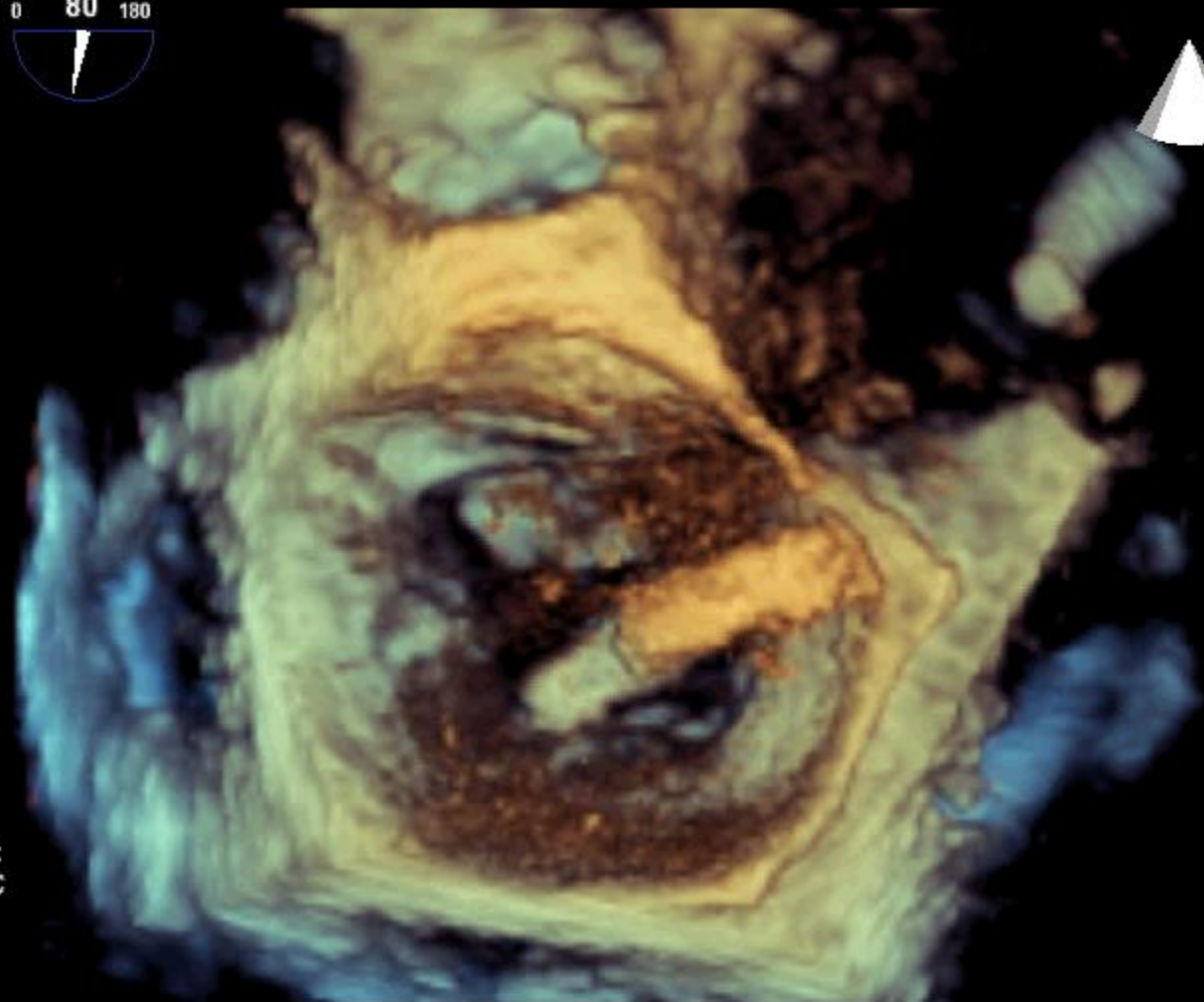
Eco adulti
X7-2t
6Hz
8.9cm

Battiti 3D 1

TIS0.0 MI 0.1

M4

Zoom 3D
2D / 3D
% 70 / 0
C 40 / 30
Gen.



PAT T: 37.0C
TEE T: 39.4C



50 bpm

Eco adulti
X7-2t
6Hz
8.9cm

Battiti 3D 1

TIS0.0 MI 0.1

M4

Zoom 3D
2D / 3D
% 68 / 5
C 40 / 30
Gen.



PAT T: 37.0C
TEE T: 39.5C

vr

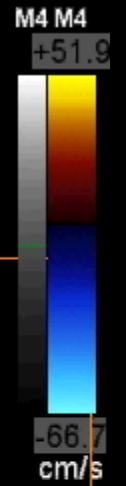
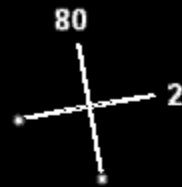
50 bpm

Eco adulti
X7-2t
15Hz
9.0cm

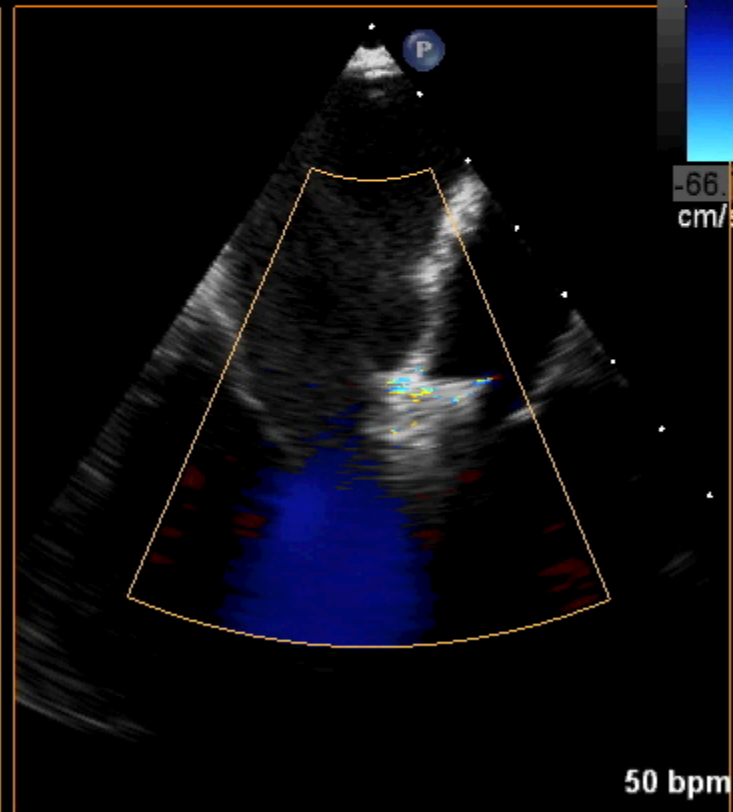
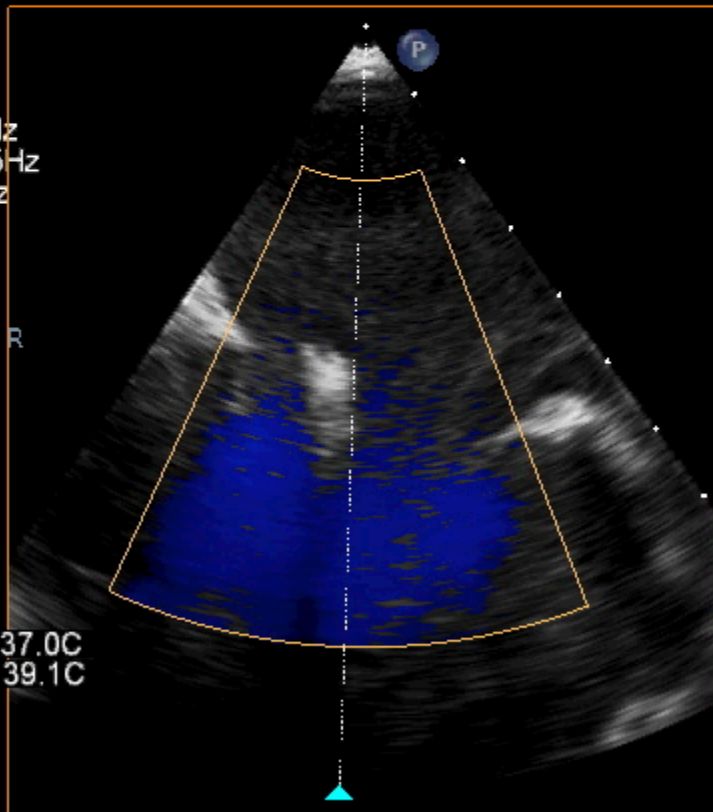
TISO.6 MI 0.3

xPlane
71%
71%
40dB
P Alto
Gen.

CF
48%
6838Hz
WF 615Hz
4.4MHz



PAT T: 37.0C
TEE T: 39.1C



50 bpm

Eco adulti
X7-2t
6Hz
7.8cm

Battiti 3D 1

TIS0.0 MI 0.1

M4



Zoom 3D
2D / 3D
% 66 / 5
C 40 / 30
Gen.



PAT T: 37.0C
TEE T: 39.4C



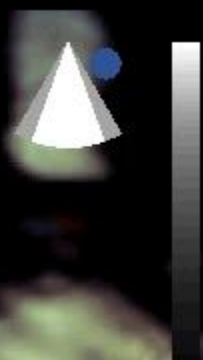
50 bpm

Eco adulti
X7-2t
6Hz
7.8cm

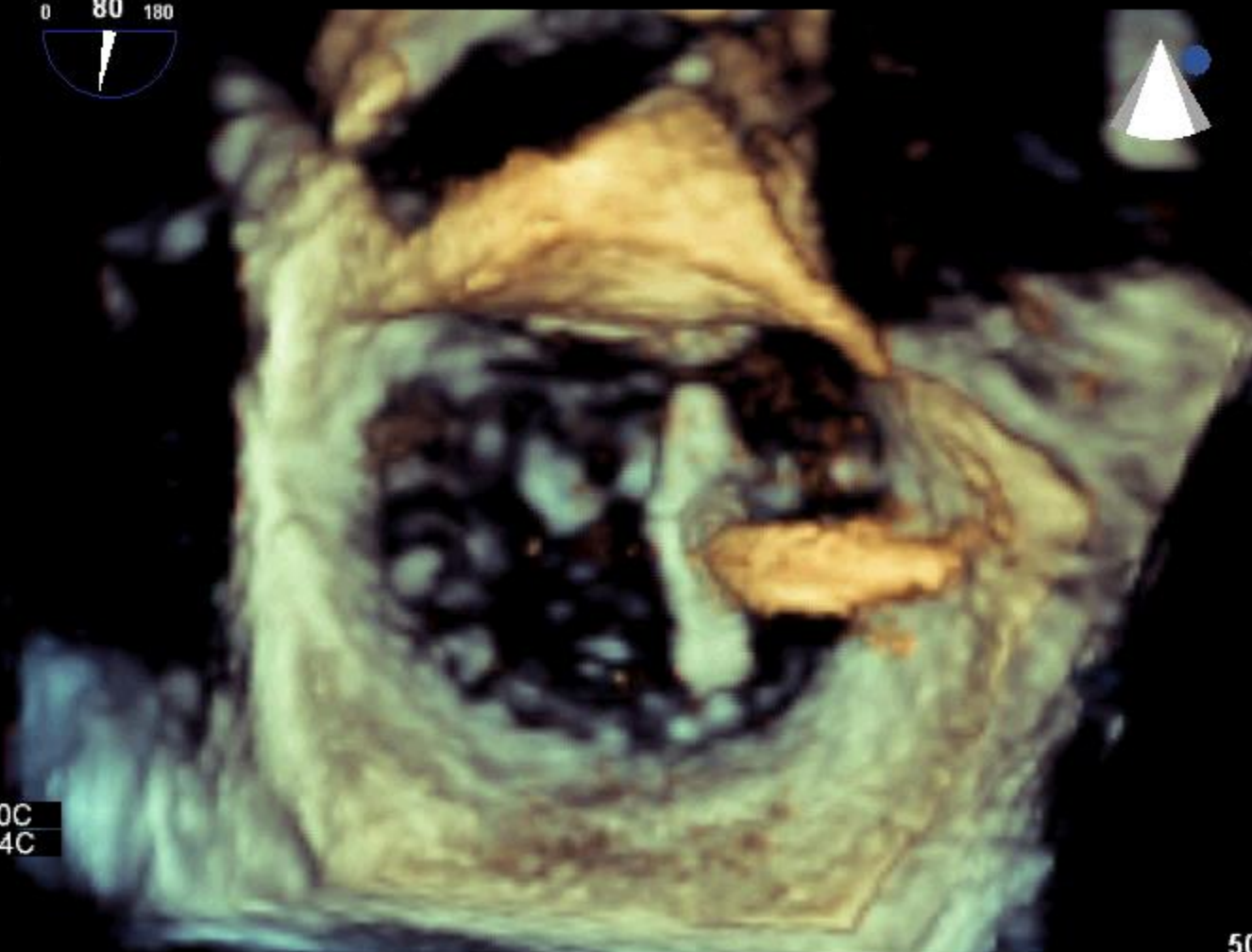
Battiti 3D 1

TIS0.0 MI 0.1

M4



Zoom 3D
2D / 3D
% 62 / 22
C 40 / 30
Gen.



PAT T: 37.0C
TEE T: 39.4C



50 bpm

ORIENTAMENTO CLIP

Eco adulti
X7-2t
6Hz
5.6cm

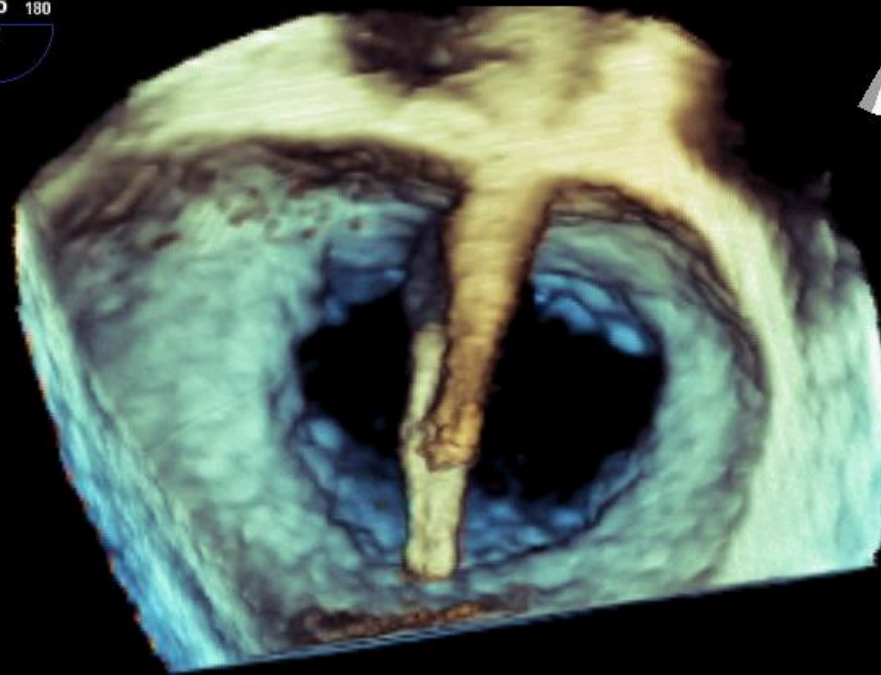
Zoom 3D
2D / 3D
% 48 / 31
C 49 / 0
Pen.



Battiti 3D 1

TIS0.1 MI 0.4

M4



PAT T: 37.0C
TEE T: 39.0C



75 bpm

Eco adulti

X7-2t

37Hz

9.0cm



TIS0.0 MI 0.1

M4



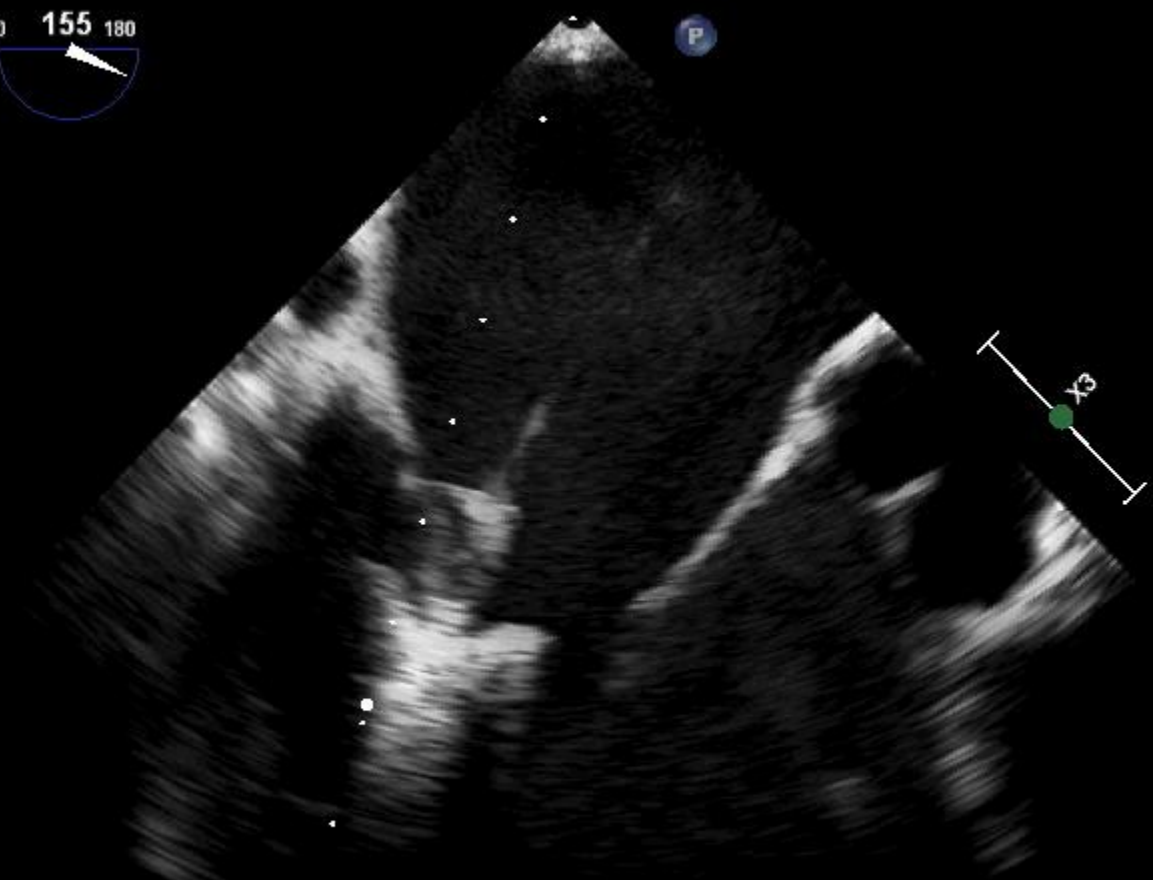
2D

70%

C 37

P Alto

Gen.



PAT T: 37.0C

TEE T: 38.7C

50 bpm

Eco adulti

X7-2t

37Hz

9.0cm



TIS0.0 MI 0.1

M4

2D

70%

C 37

P Alto

Gen.



PAT T: 37.0C

TEE T: 38.7C

|

50 bpm

Eco adulti

X7-2t

37Hz

9.0cm



TIS0.0 MI 0.1

M4



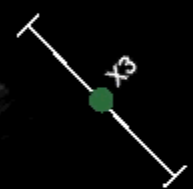
2D

70%

C 37

P Alto

Gen.



PAT T: 37.0C

TEE T: 38.7C

!

50 bpm

Eco adulti

X7-2t

37Hz

9.0cm



TIS0.0 MI 0.1

M4



2D

70%

C 37

P Alto

Gen.



PAT T: 37.0C

TEE T: 38.6C

!

50 bpm

Eco adulti

X7-2t

37Hz

9.0cm



TIS0.0 MI 0.1

M4



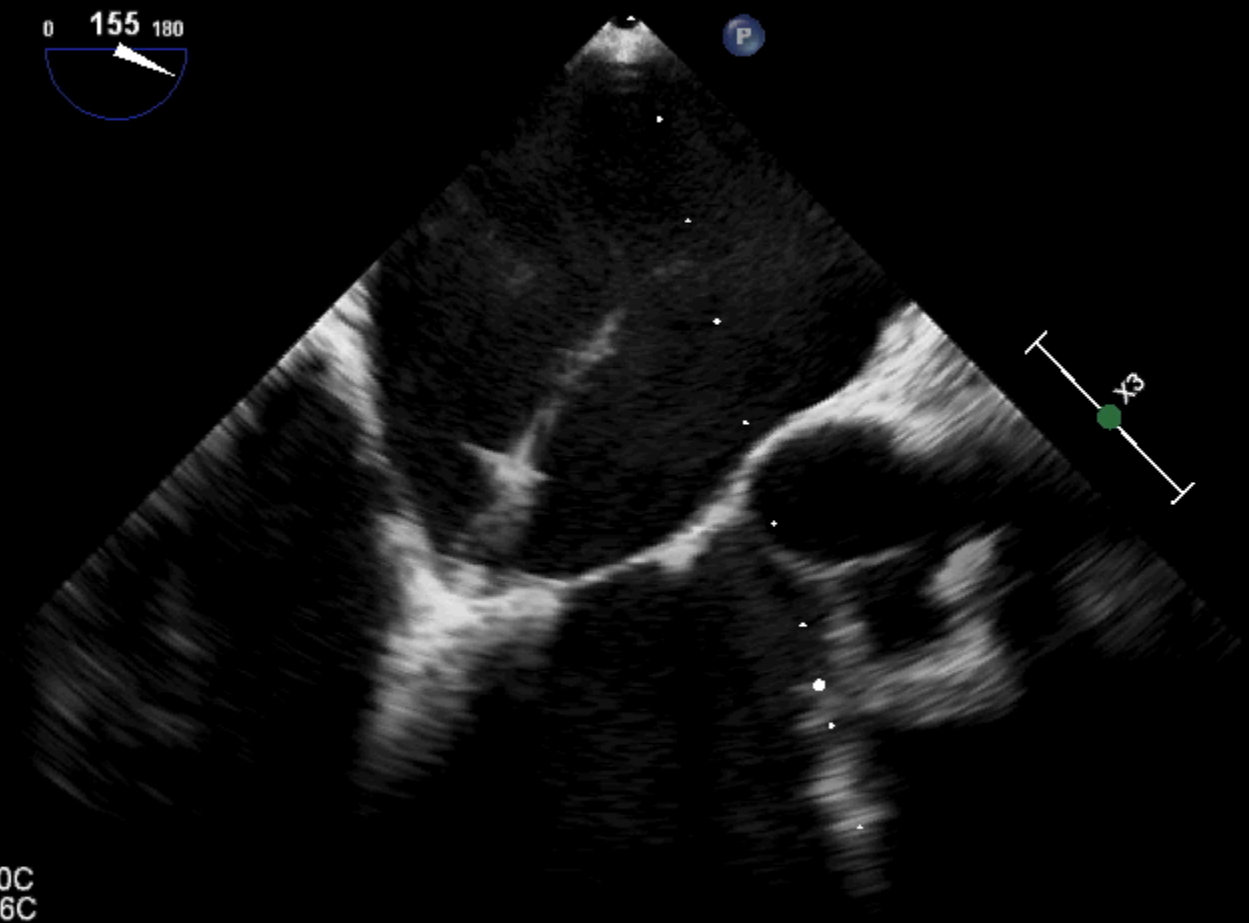
2D

70%

C 37

P Alto

Gen.



PAT T: 37.0C

TEE T: 38.6C

!

50 bpm

Eco adulti

X7-2t

37Hz

9.0cm



TIS0.0 MI 0.1

M4

2D

70%

C 37

P Alto

Gen.



PAT T: 37.0C

TEE T: 38.5C

1

50 bpm

Eco adulti

X7-2t

37Hz

9.0cm



TIS0.0 MI 0.1

M4

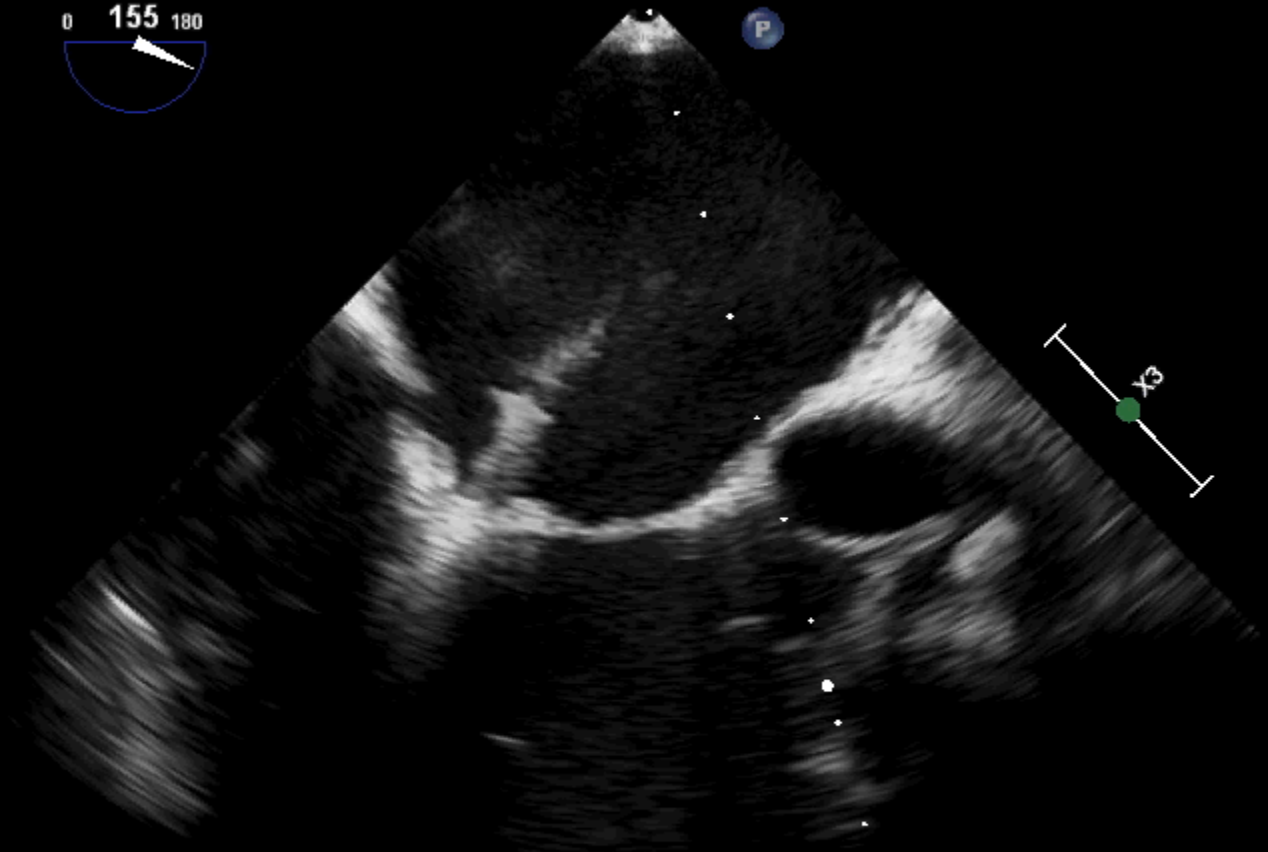
2D

70%

C 37

P Alto

Gen.



PAT T: 37.0C

TEE T: 38.5C

50 bpm

Eco adulti

X7-2t

37Hz

9.0cm



TIS0.0 MI 0.1

M4



2D

70%

C 37

P Alto

Gen.



PAT T: 37.0C

TEE T: 38.5C

!

50 bpm

Eco adulti

X7-2t

37Hz

9.0cm

2D

70%

C 37

P Alto

Gen.



TIS0.0 MI 0.1

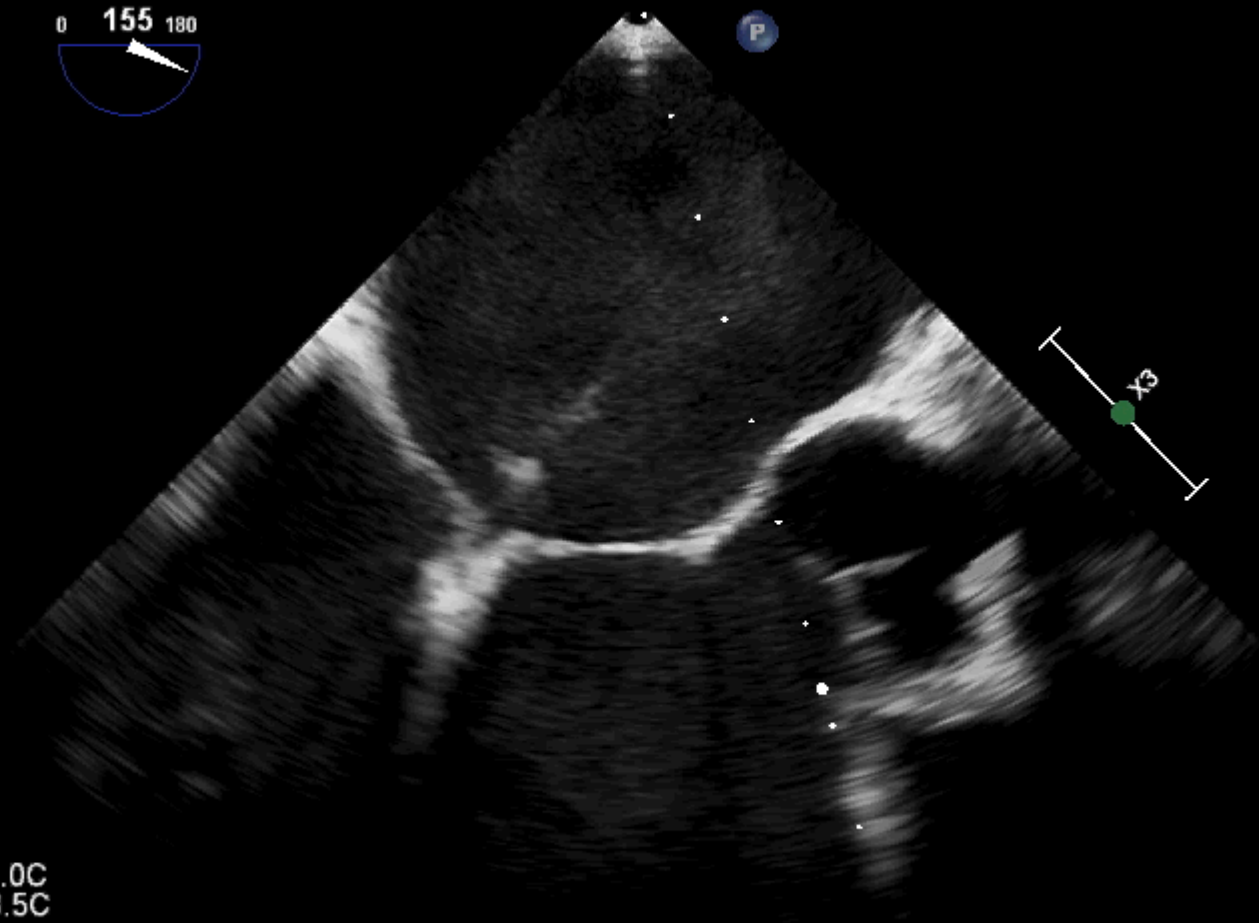
M4



PAT T: 37.0C
TEE T: 38.5C

!

53 bpm



Eco adulti

X7-2t

37Hz

9.0cm

2D

74%

C 37

P Alto

Gen.

TIS0.0 MI 0.1

M4



PAT T: 37.0C
TEE T: 38.7C

50 bpm

Eco adulti

X7-2t

37Hz

9.0cm



TISO.0 MI 0.1

M4



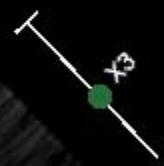
2D

74%

C 37

P Alto

Gen.



PAT T: 37.0C
TEE T: 38.7C

!

50 bpm

Eco adulti

X7-2t

37Hz

9.0cm

2D

74%

C 37

P Alto

Gen.

TIS0.0 MI 0.1

M4



PAT T: 37.0C
TEE T: 38.7C

1

50 bpm



Eco adulti

X7-2t

37Hz

9.0cm

2D

74%

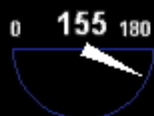
C 37

P Alto

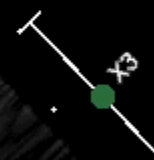
Gen.

TIS0.0 MI 0.1

M4



P



PAT T: 37.0C
TEE T: 38.7C

50 bpm

Eco adulti

X7-2t

30Hz

9.0cm



2D

78%

C 37

P Alto

Gen.

CF

48%

6838Hz

WF 615Hz

4.4MHz



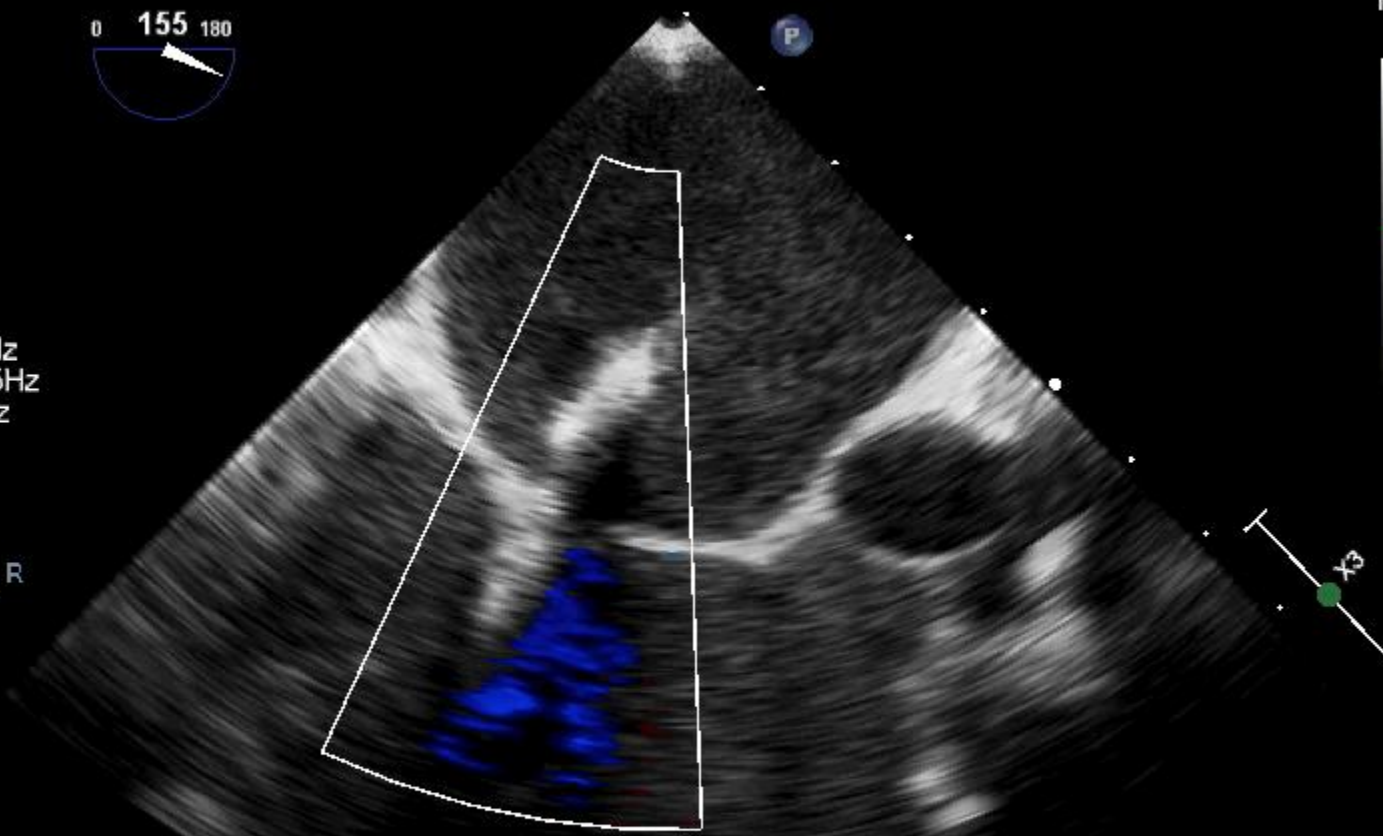
TISO.6 MI 0.3

M4 M4

+51.9



cm/s



PAT T: 37.0C

TEE T: 38.8C

1

50 bpm

Eco adulti

X7-2t

27Hz

9.0cm



TISO.6 MI 0.3

2D

75%

C 37

P Alto

Gen.

CF

48%

6838Hz

WF 615Hz

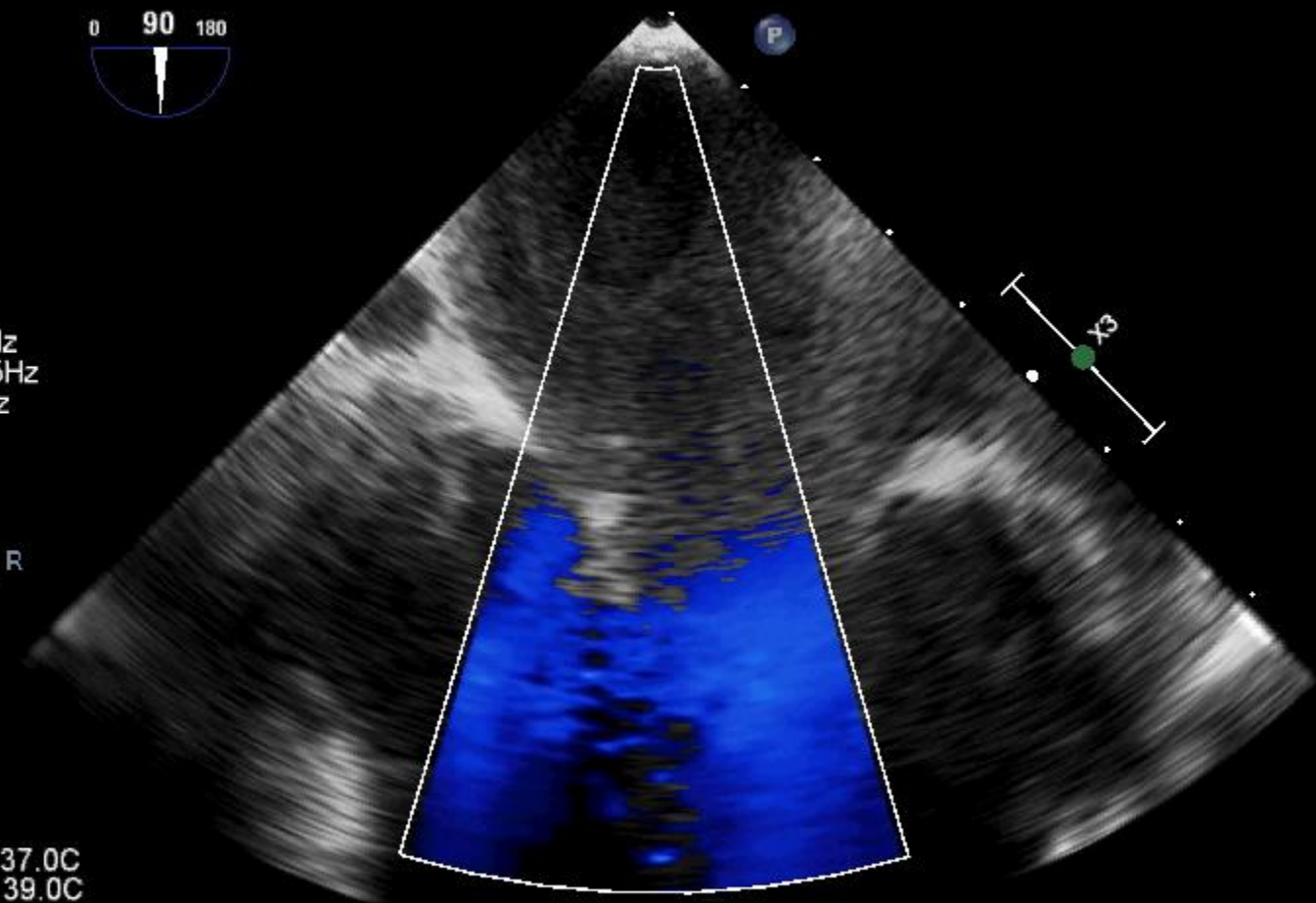
4.4MHz

M4 M4

+51.9



cm/s



PAT T: 37.0C

TEE T: 39.0C

50 bpm

Eco adulti

X7-2t

66Hz

9.0cm

xPlane

70%

70%

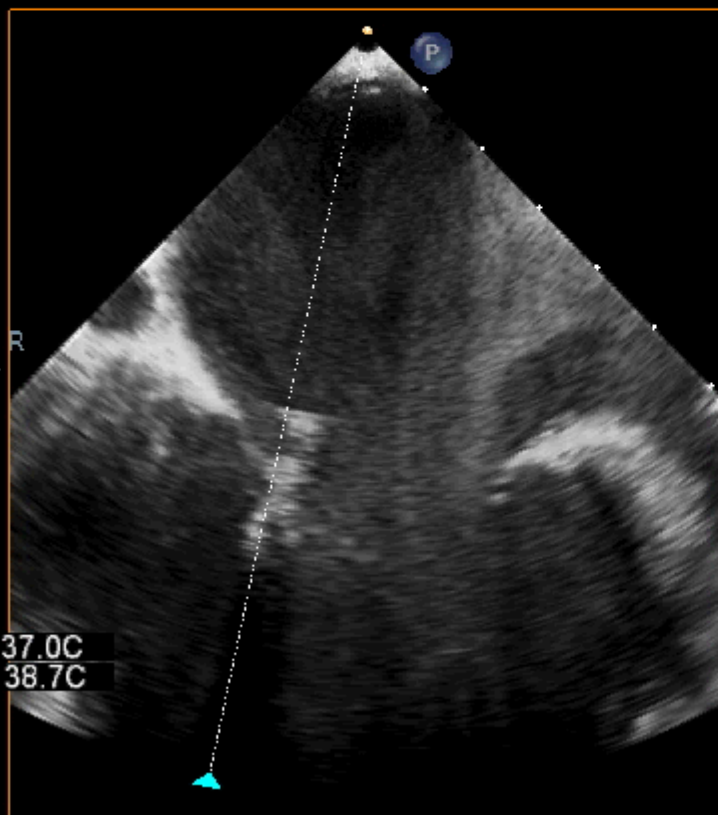
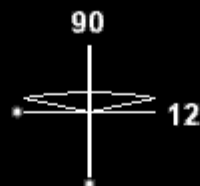
37dB

P Alto

Gen.

TISO.1 MI 0.2

M4

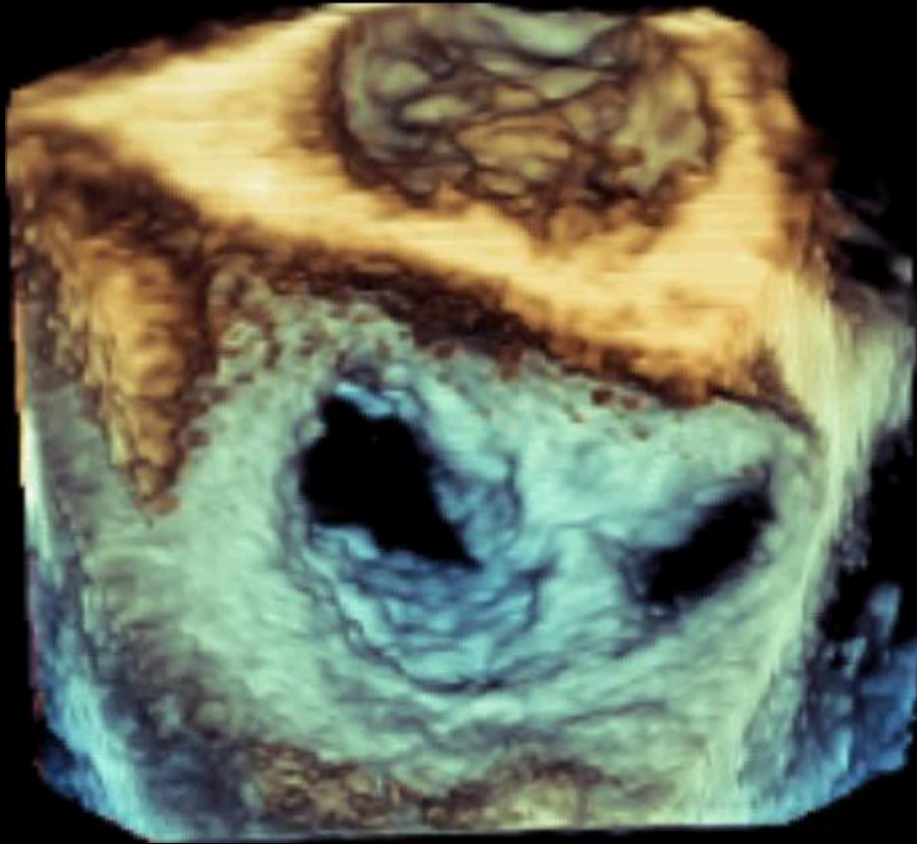


PAT T: 37.0C
TEE T: 38.7C

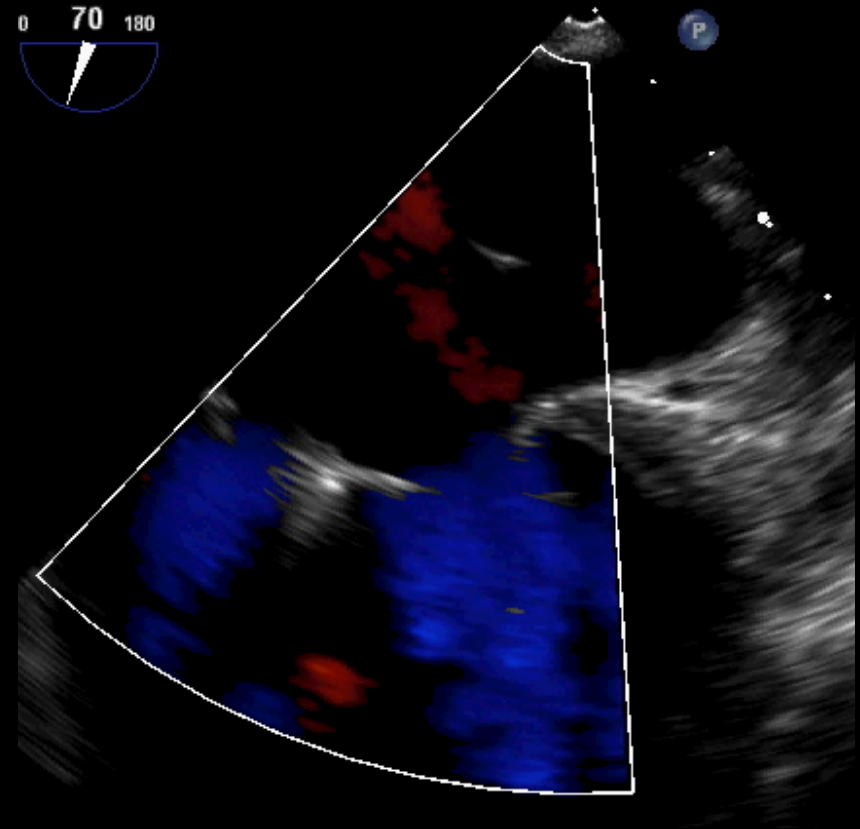
50 bpm

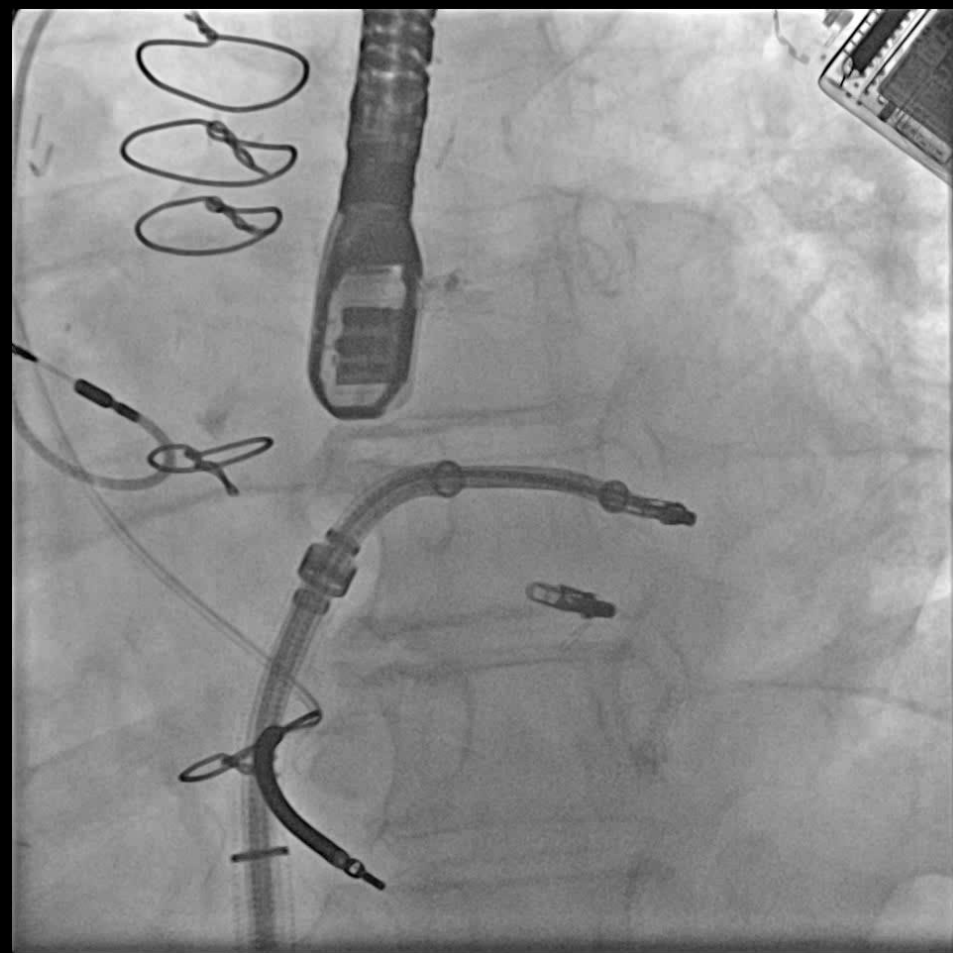
MITRACLIP

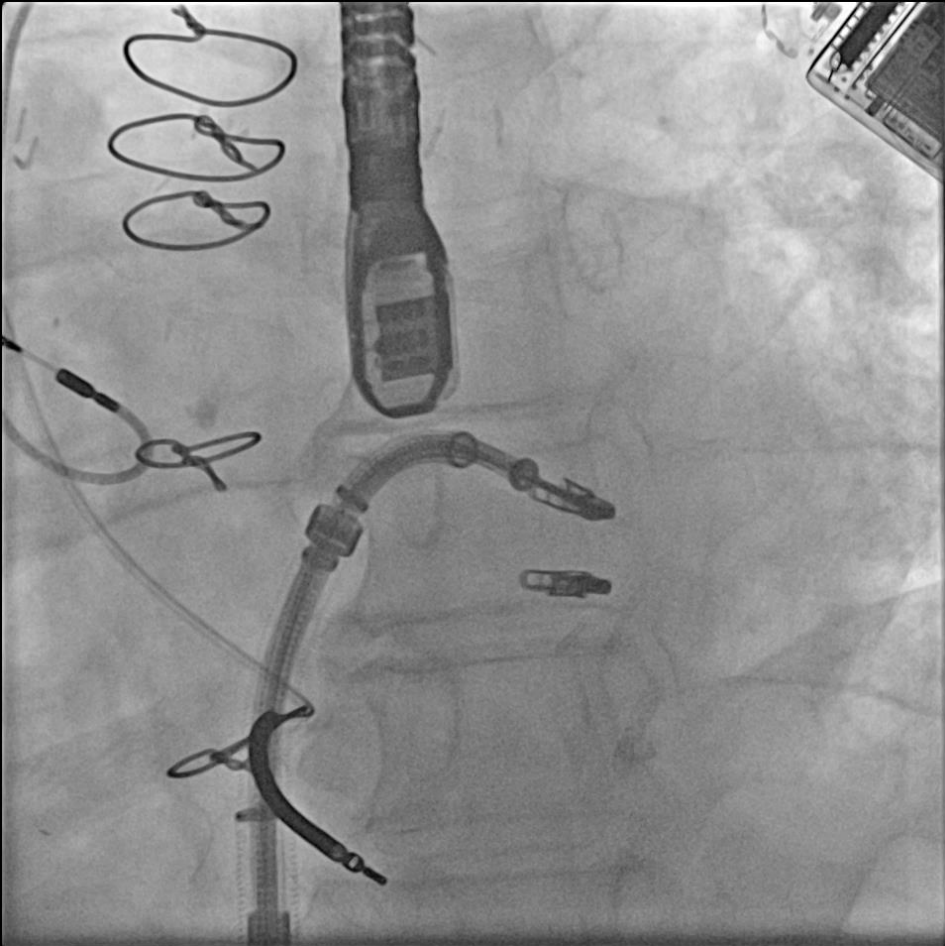
CLIP 1



IM RESIDUA









Eco adulti

X7-2t

56Hz

11cm

Z 1.4

xPlane

67%

67%

45dB

P Alto

AGen

TISO.1 MI 0.5

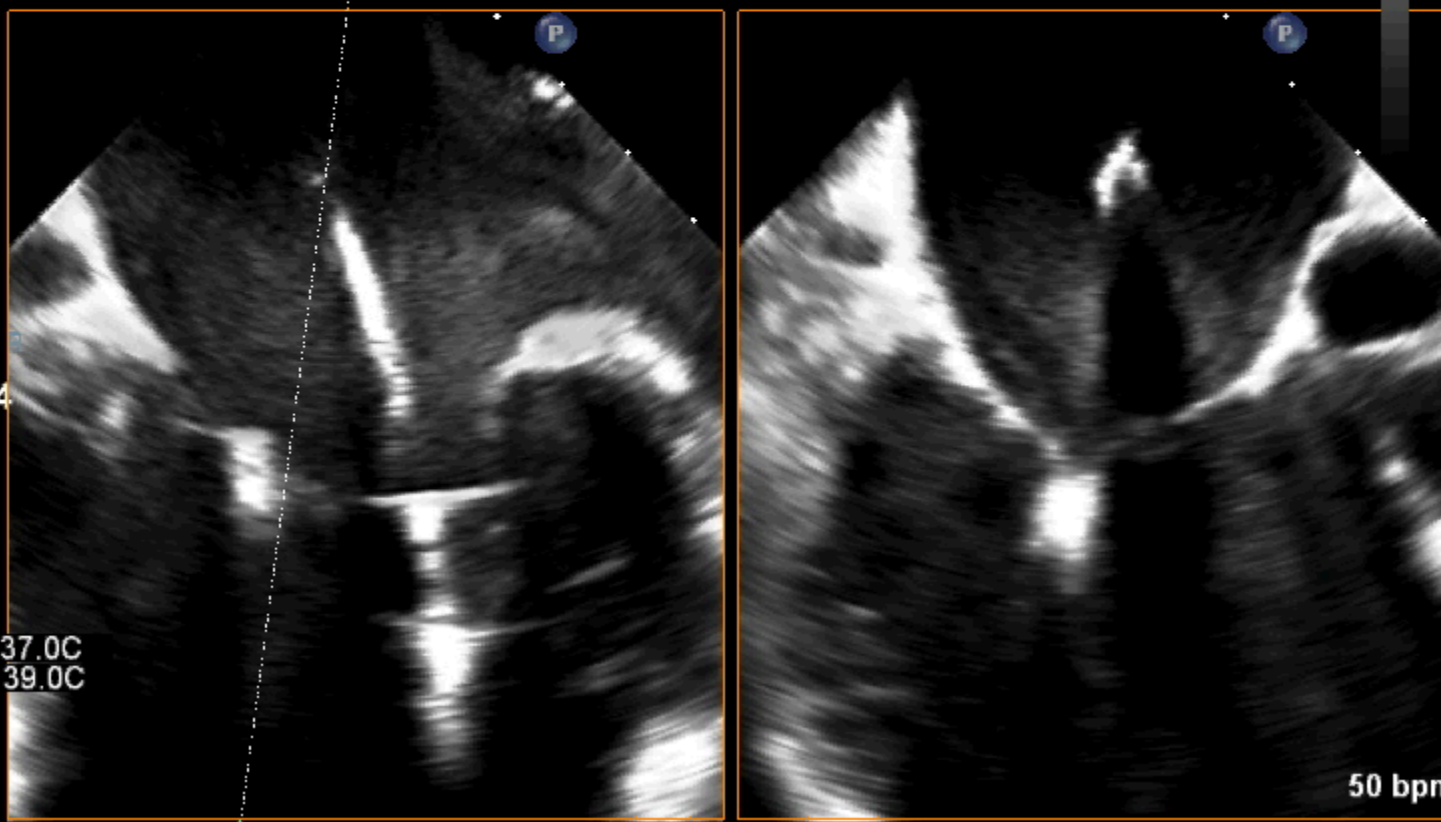
M4

80

8



PAT T: 37.0C
TEE T: 39.0C



50 bpm

Eco adulti

X7-2t

56Hz

11cm

Z 1.7

xPlane

67%

67%

45dB

P Alto

AGen

TISO.1 MI 0.2

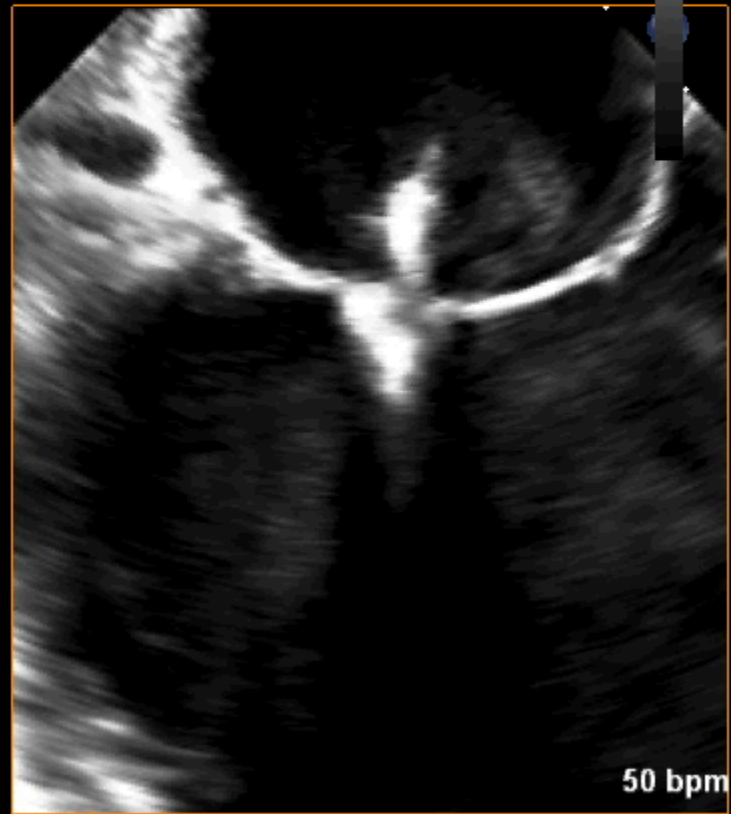
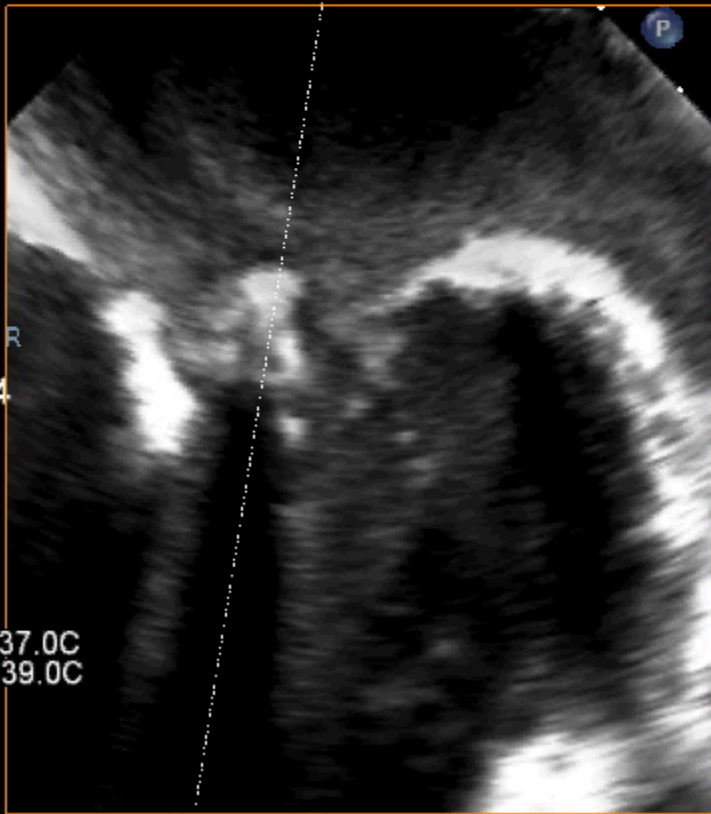
M4

80

9



PAT T: 37.0C
TEE T: 39.0C



50 bpm

Eco adulti

X7-2t

16Hz

11cm

xPlane

72%

72%

45dB

P Alto

AGen

CF

48%

6838Hz

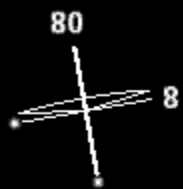
WF 615Hz

4.4MHz



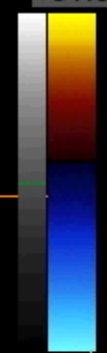
PAT T: 37.0C
TEE T: 38.9C

TISO.1 MI 0.1



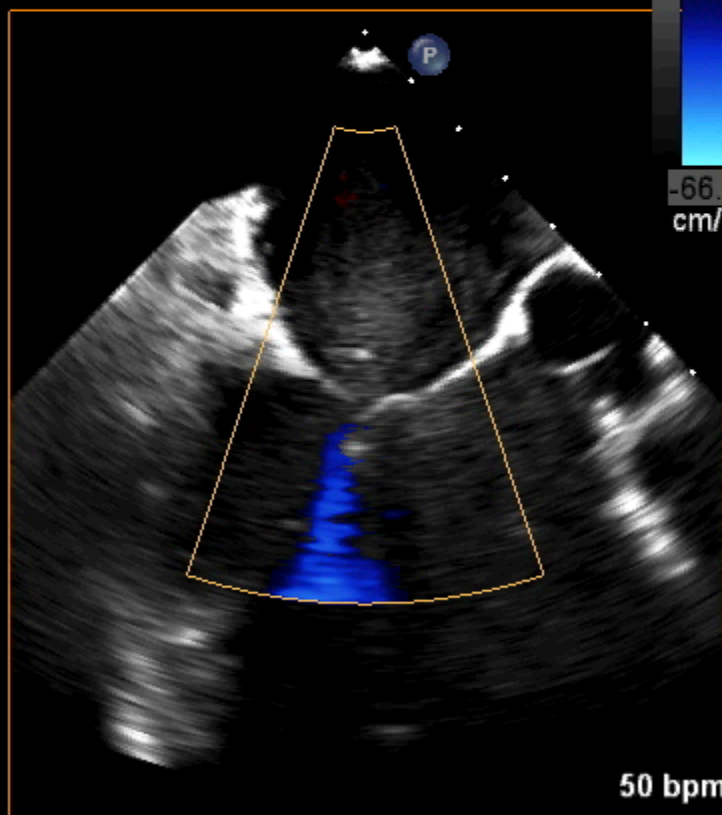
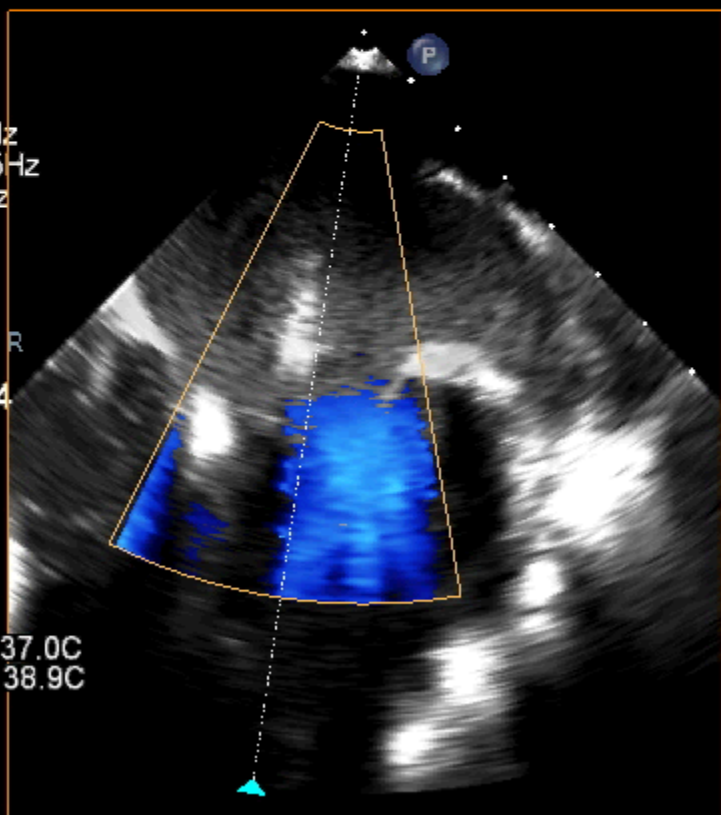
M4 M4

+51.9



-66.7

cm/s



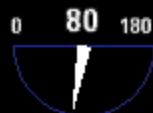
50 bpm

Eco adulti

X7-2t

22Hz

9.0cm



2D

67%

C 45

P Alto

AGen

CF

48%

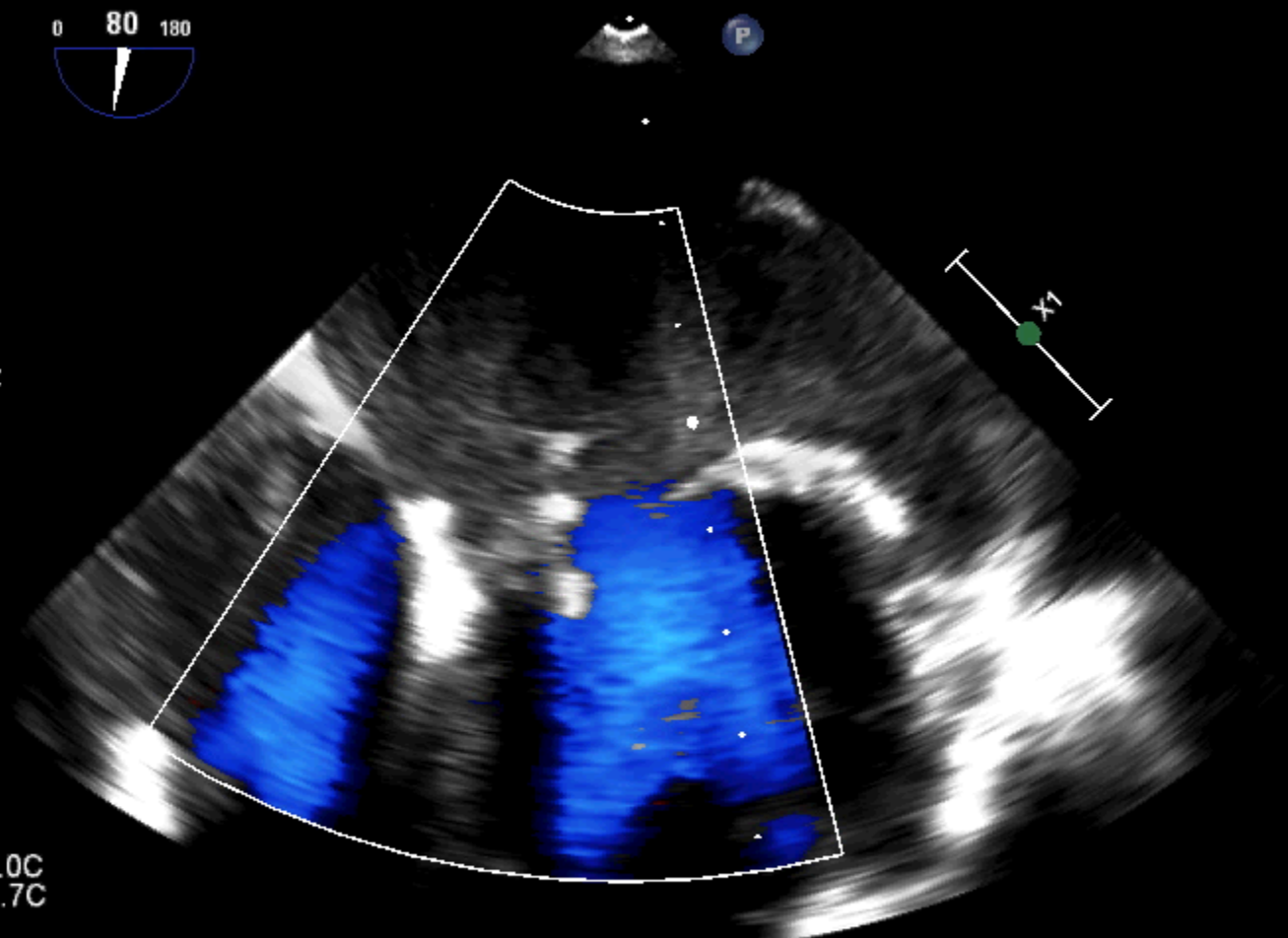
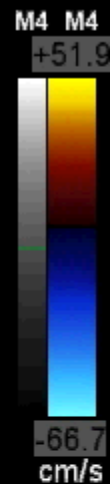
6838Hz

WF 615Hz

4.4MHz



TISO.1 MI 0.1



PAT T: 37.0C
TEE T: 38.7C

50 bpm

Eco adulti

X7-2t

15Hz

10cm

xPlane

76%

76%

45dB

P Alto

AGen

CF

48%

6710Hz

WF 603Hz

4.4MHz



2.7 5.4

PAT T: 37.0C

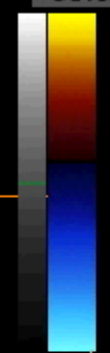
TEE T: 38.0C

TIS0.1 MI 0.2

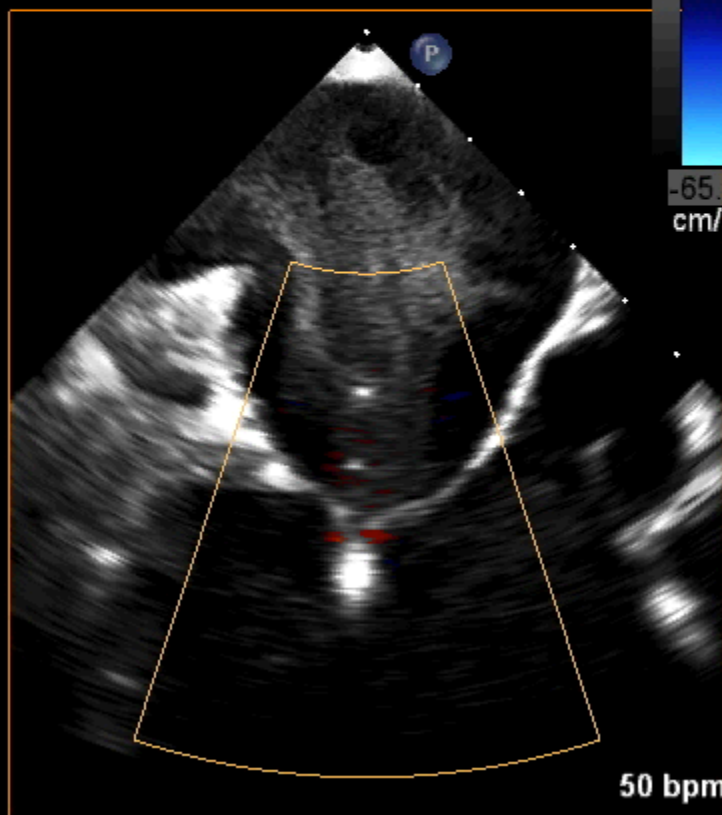
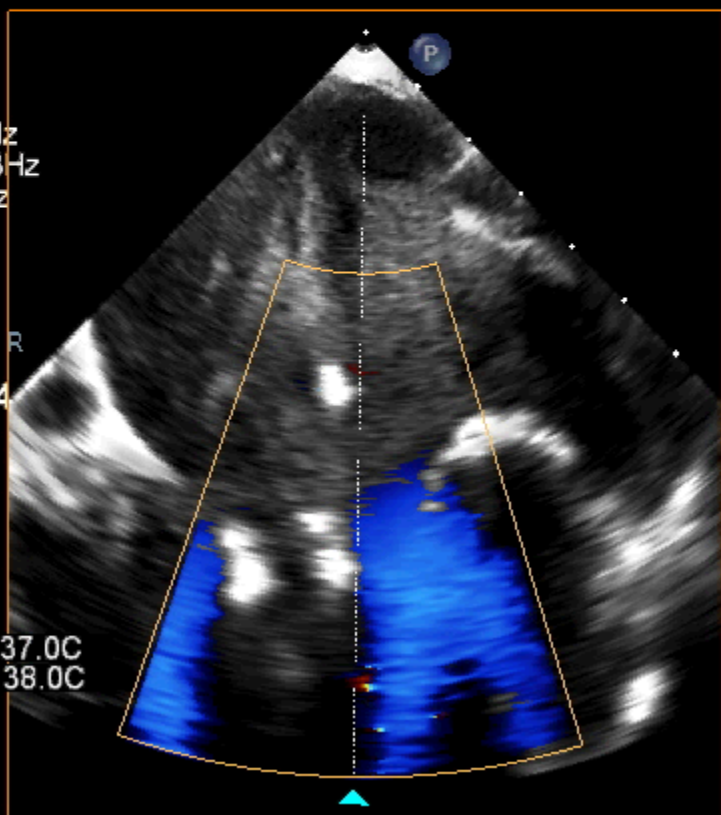


M4 M4

+50.9



-65.5
cm/s



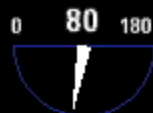
50 bpm

Eco adulti

X7-2t

23Hz

11cm



2D

68%

C 51

P Alto

AGen

CF

48%

6263Hz

WF 563Hz

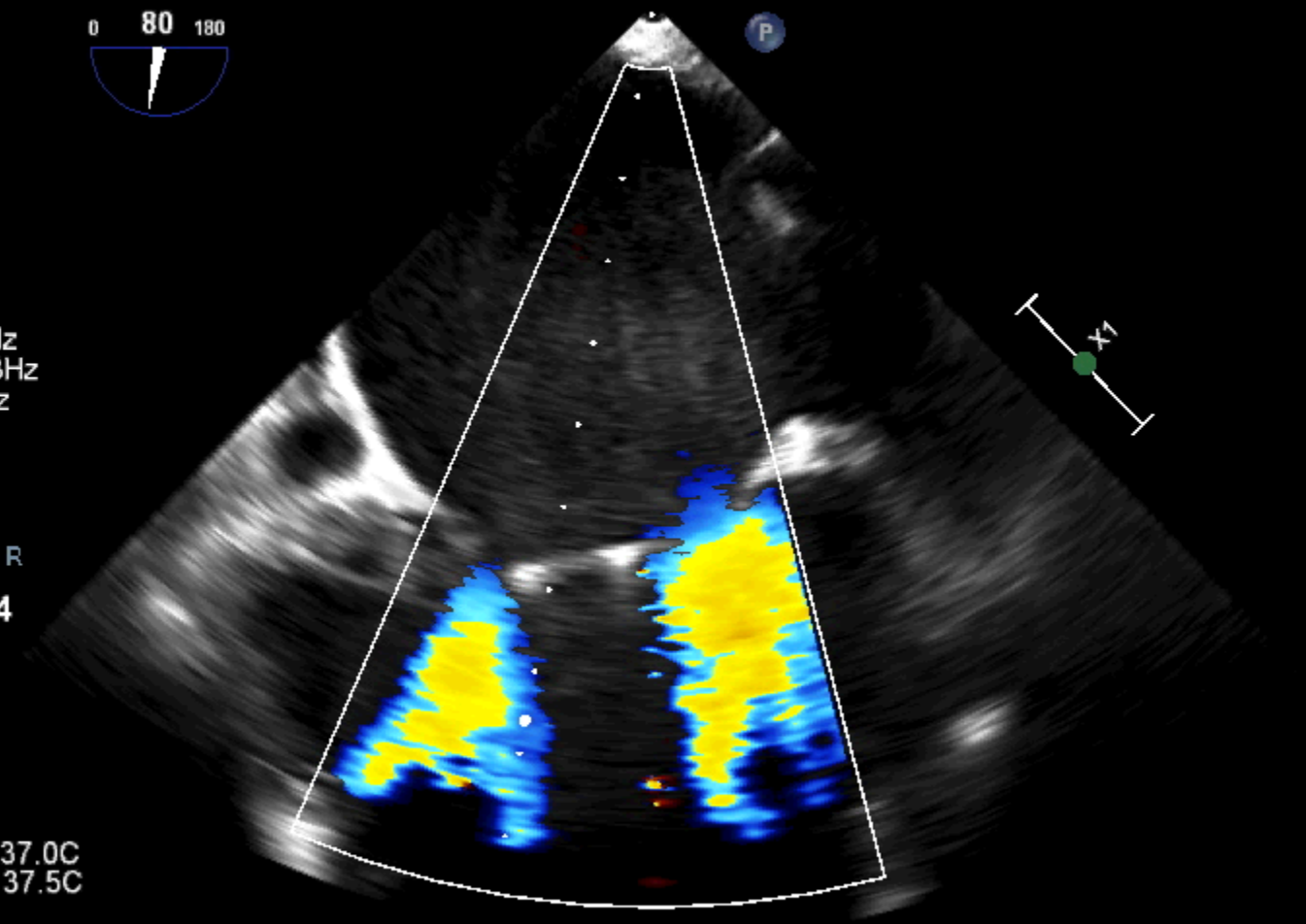
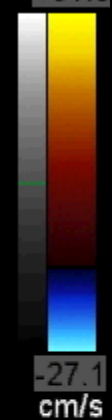
4.4MHz



TISO.1 MI 0.1

M4 M4

+81.5



PAT T: 37.0C

TEE T: 37.5C

50 bpm

Eco adulti

X7-2t

21Hz

11cm



TISO.1 MI 0.1

2D

68%

C 51

P Alto

AGen

CF

48%

6218Hz

WF 559Hz

4.4MHz

M4 M4

+80.9



cm/s



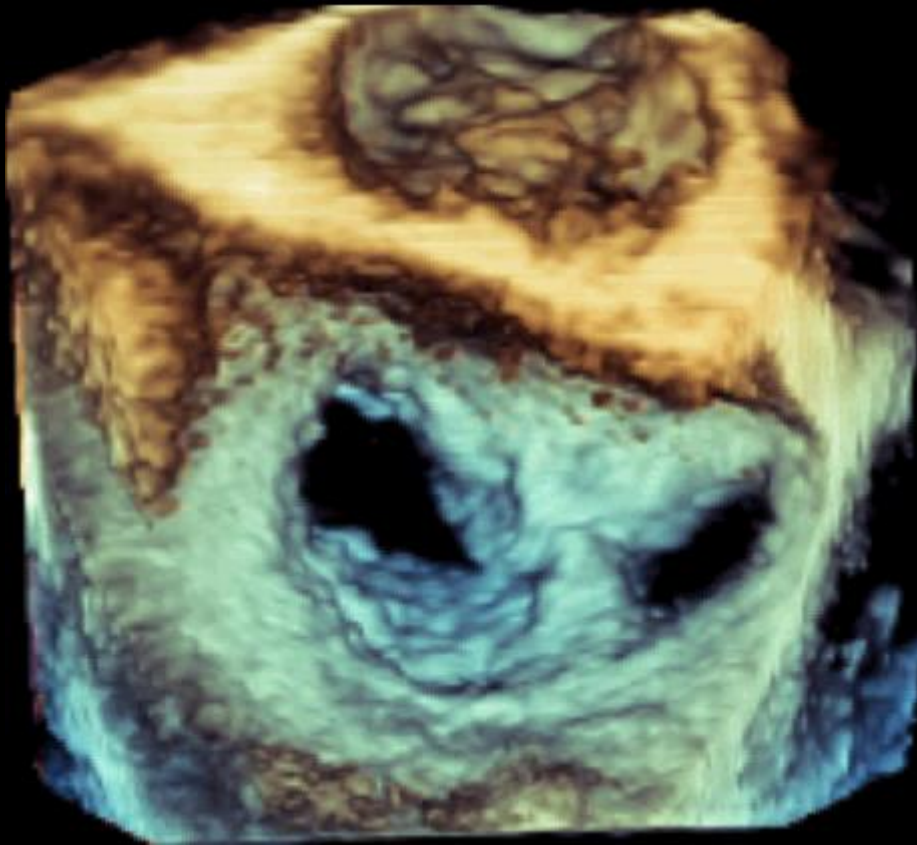
PAT T: 37.0C

TEE T: 37.5C

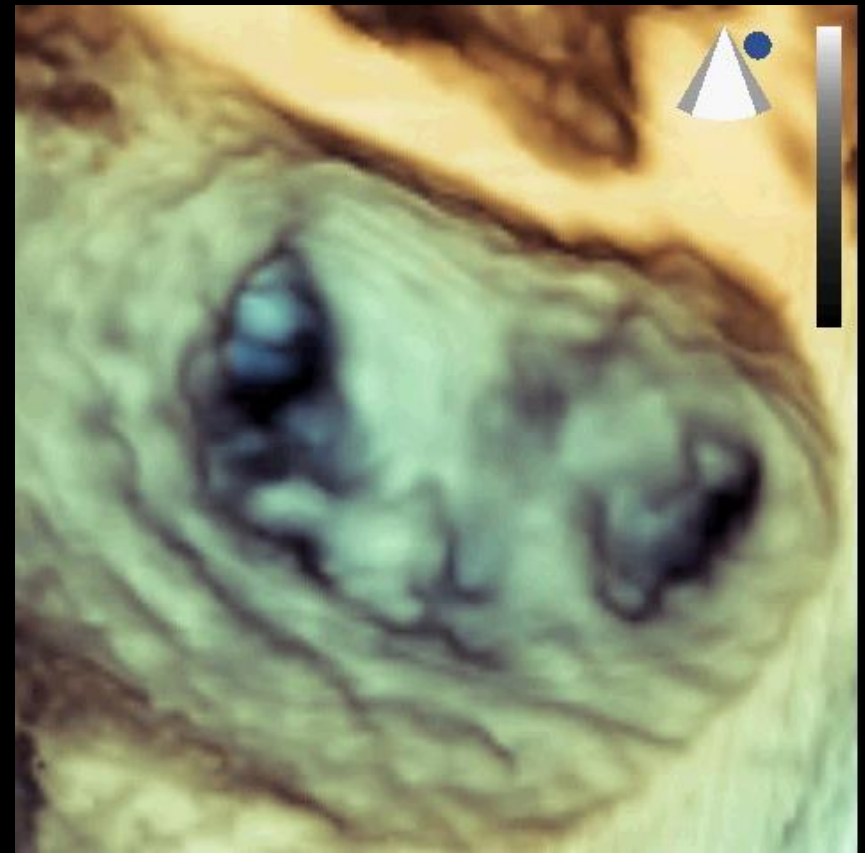
50 bpm

MITRACLIP

CLIP 1

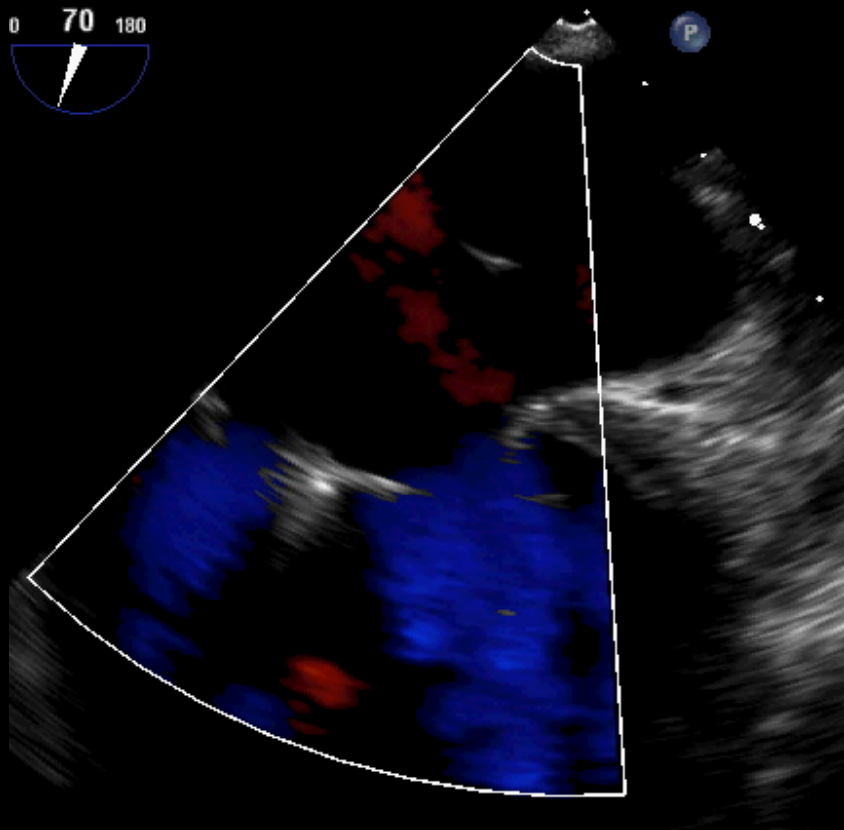


CLIP 2

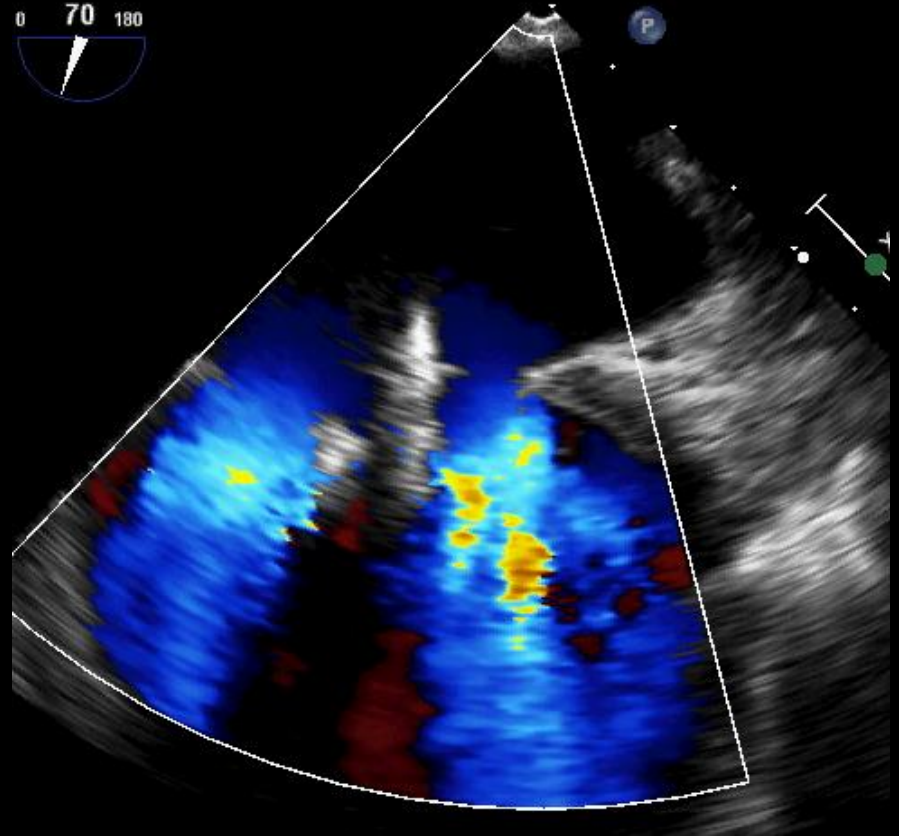


MITRACLIP

CLIP 1 - IM RESIDUA

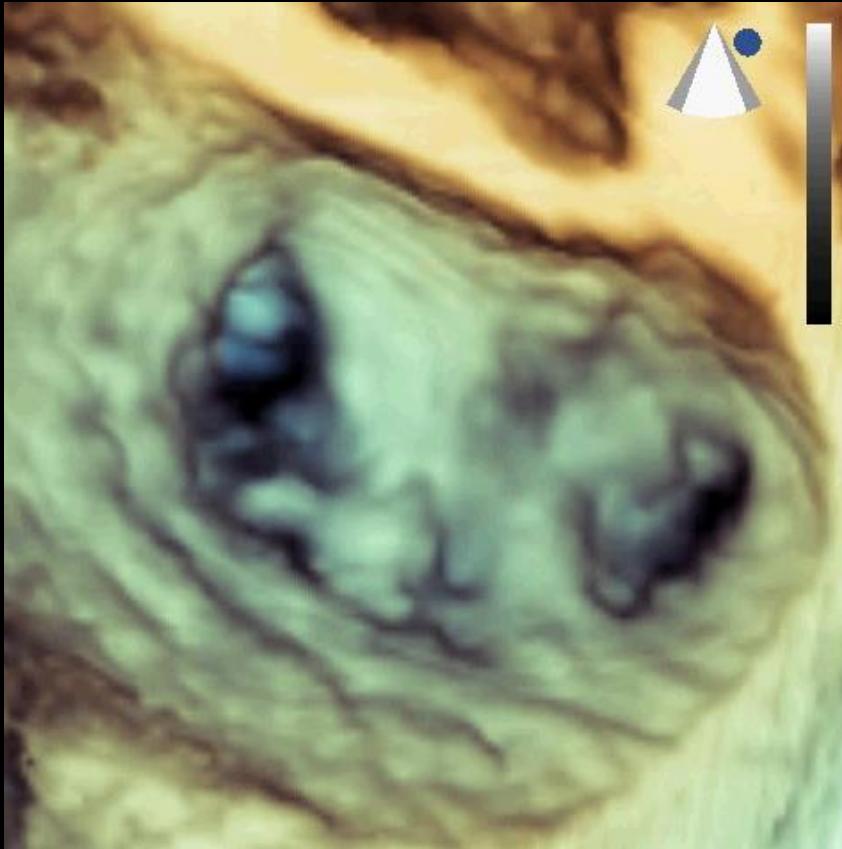


CLIP 2 - IM RESIDUA

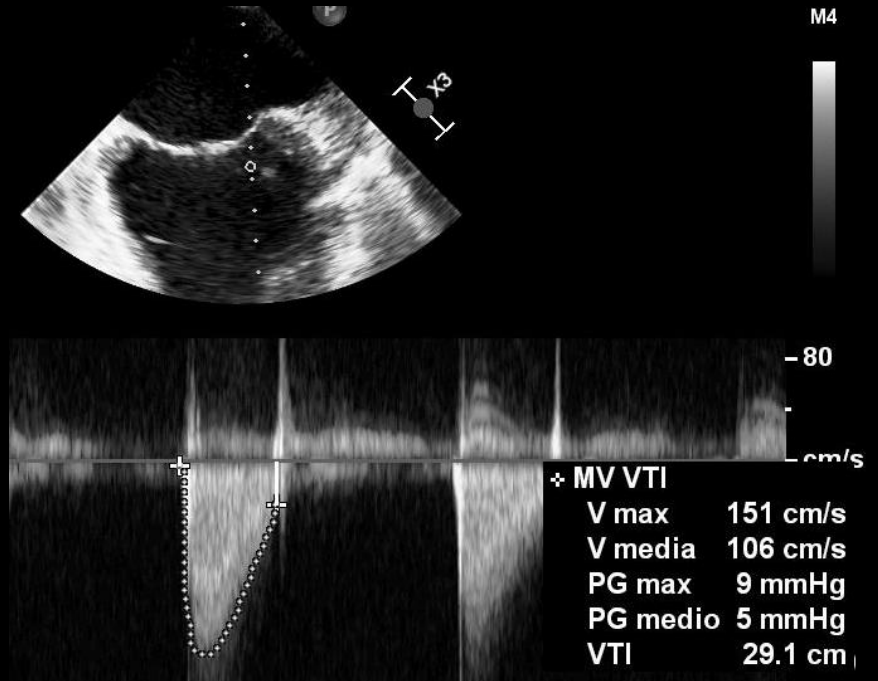


MITRACLIP

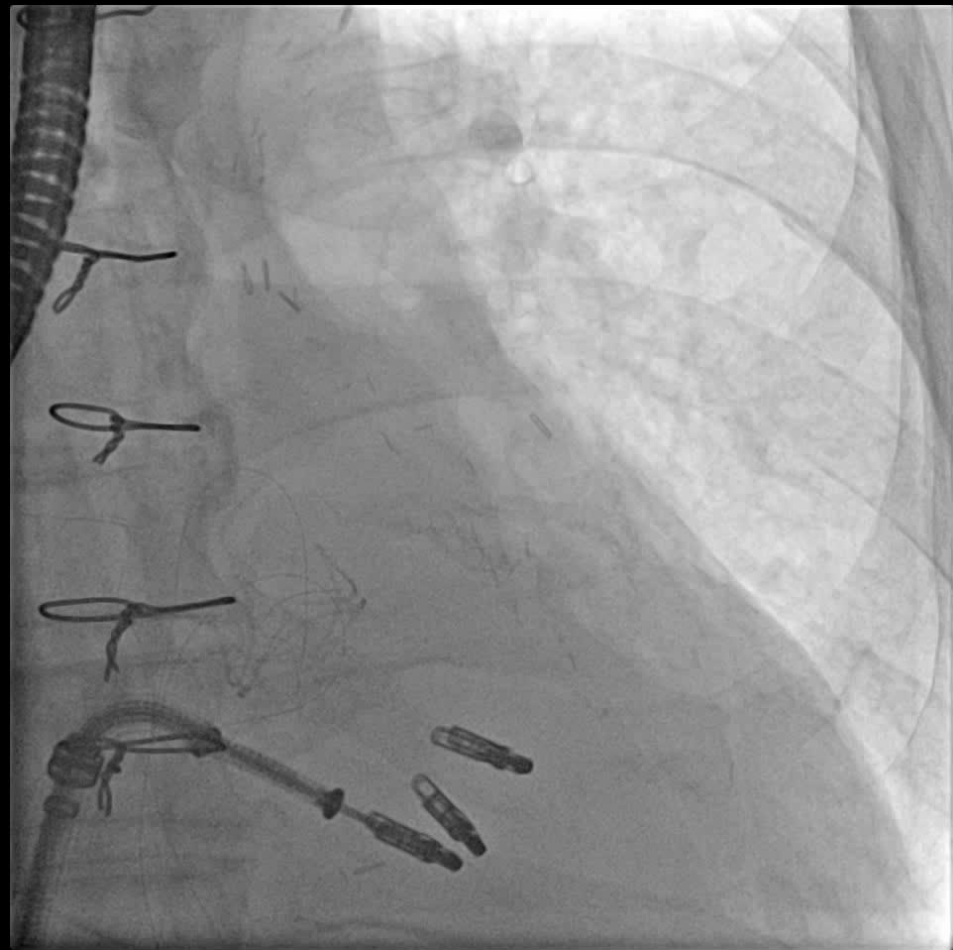
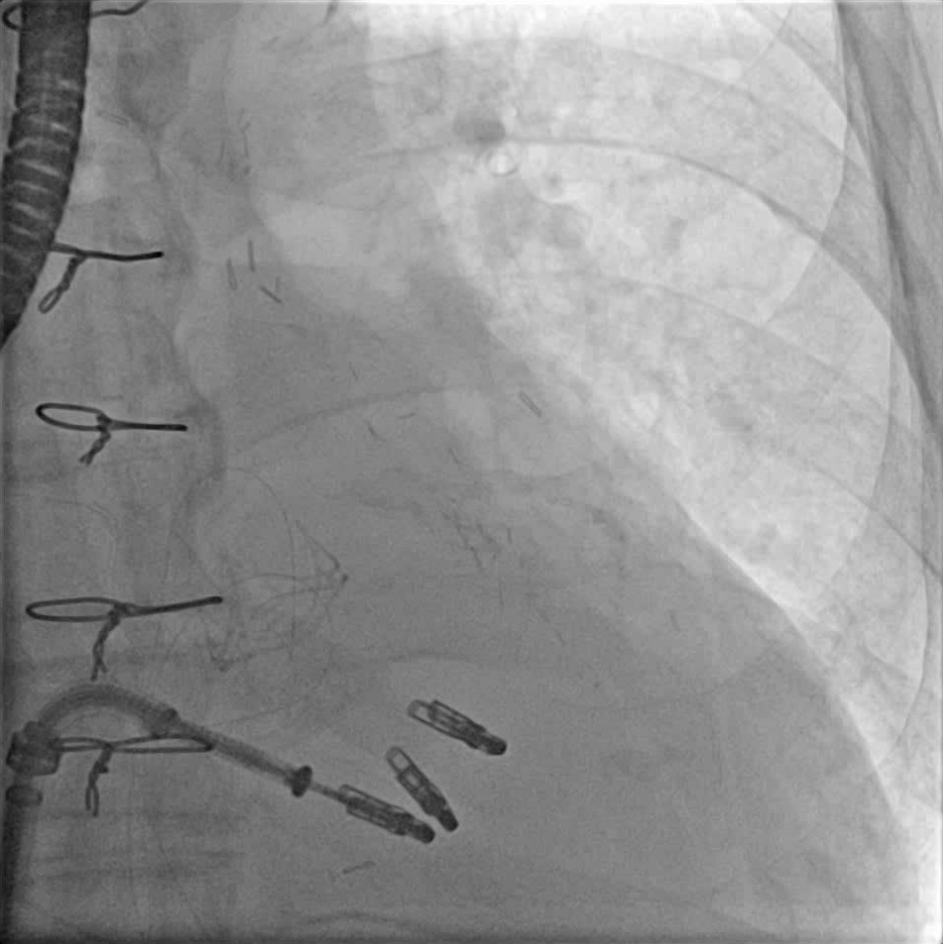
CLIP 2



CW doppler transmitralico



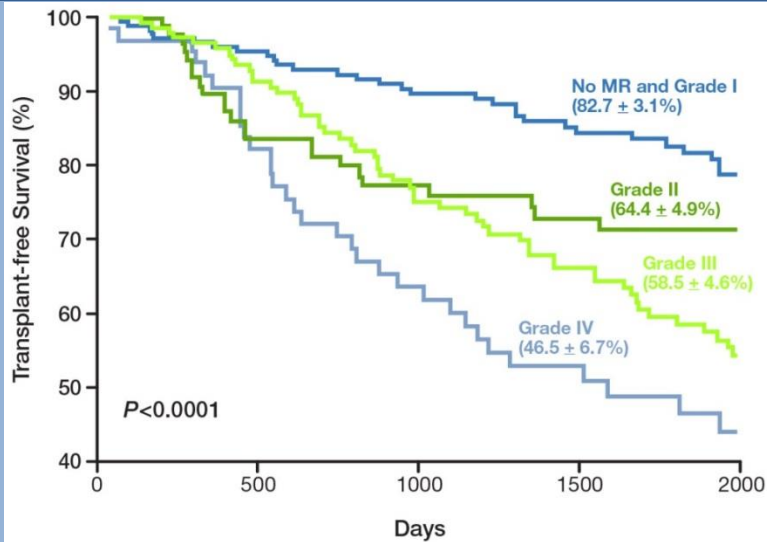
Gradiente medio 5 mmHg



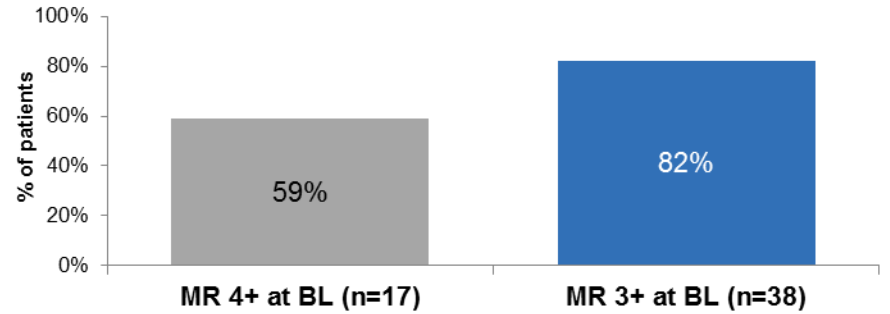
Risultati

Event – free survival decreases with increasing MR severity^{1,2,3}

MitraClip intervention in less severe MR results in better outcomes⁴

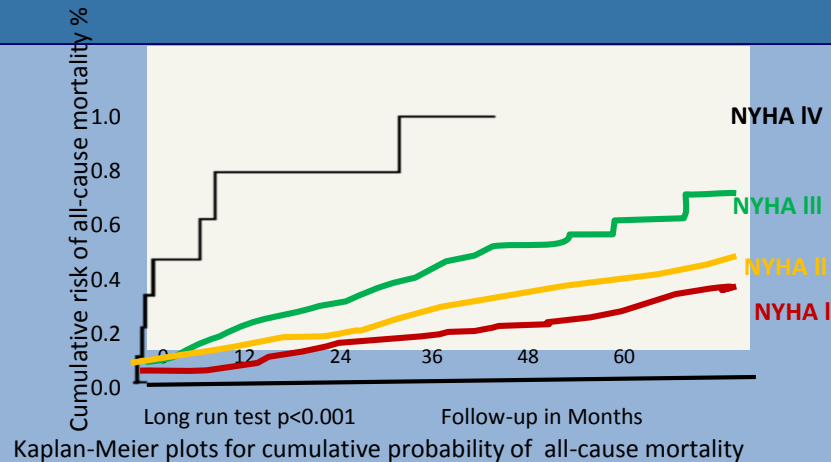


Δ23% MitraClip patients with MR ≤2+ at 1 year

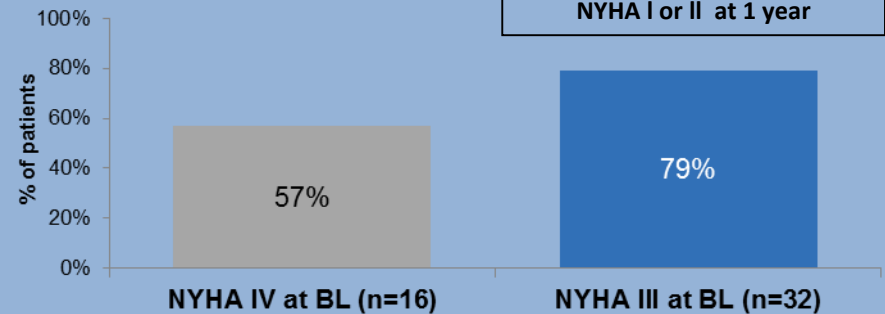


Risk of mortality increases with increasing NYHA class

For patients with MR≥3+, MitraClip intervention in less severe NYHA class results in better outcomes



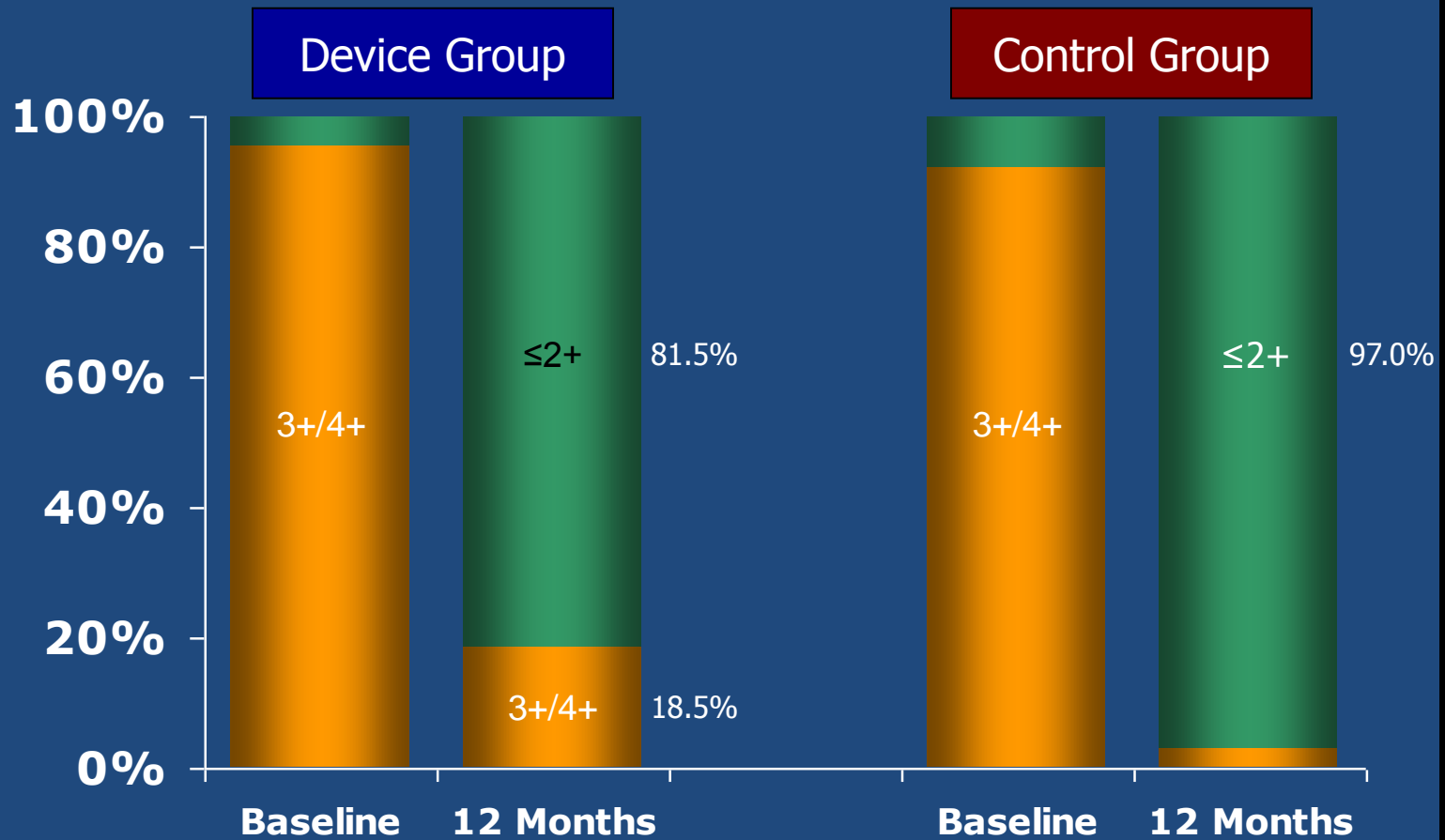
Δ22% MitraClip patients with NYHA I or II at 1 year



Patients in NYHA class I and II at 12 months

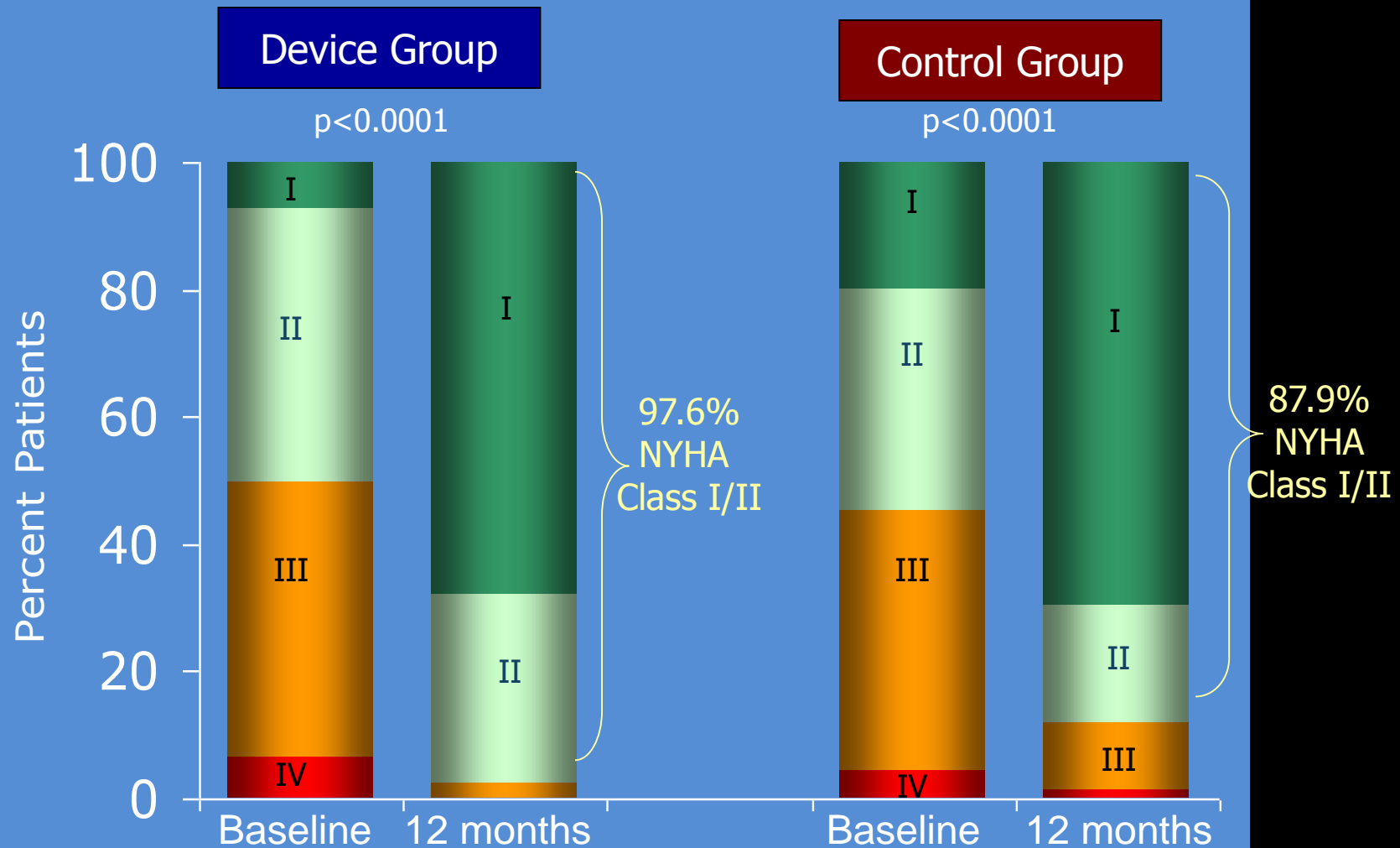
EVEREST II RCT: MR Reduction

Per Protocol Cohort



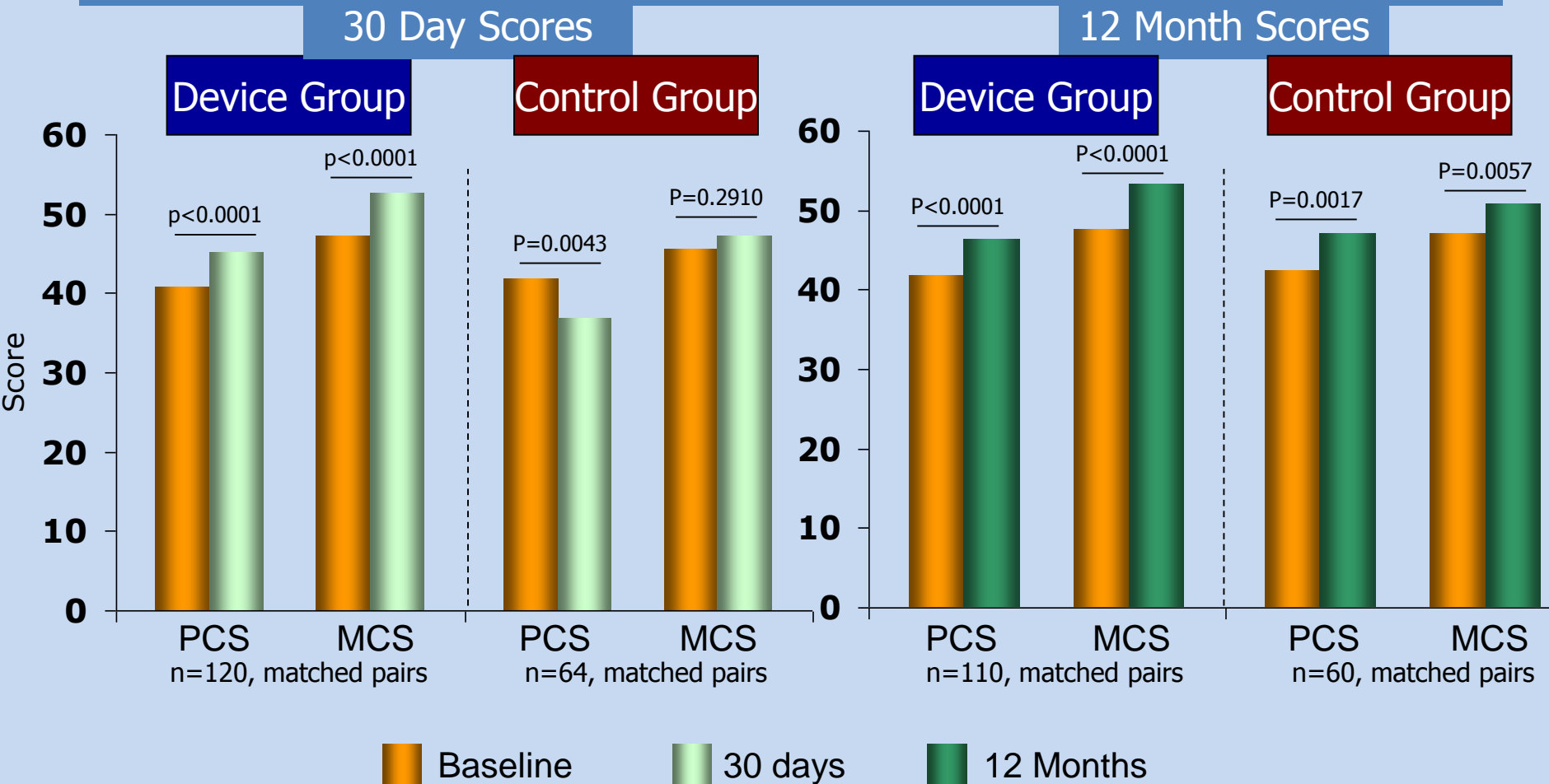
EVEREST II RCT: NYHA Functional Class

Per Protocol Cohort



EVEREST II RCT: Quality of Life, SF-36 Survey

Per Protocol Cohort



PSC = Physical Component Summary
MCS = Mental Component Summary

EVEREST II RCT: Conclusion

The MitraClip procedure is an important therapeutic option for selected patients with significant mitral regurgitation given the demonstrated safety, effectiveness and clinical benefit.

1.0 INDICATION FOR USE

The MitraClip® NT Clip Delivery System is indicated for the percutaneous reduction of significant symptomatic mitral regurgitation (MR ≥ 3+) due to primary abnormality of the mitral apparatus [degenerative MR] in patients who have been determined to be at prohibitive risk for mitral valve surgery by a heart team, which includes a cardiac surgeon experienced in mitral valve surgery and a cardiologist experienced in mitral valve disease, and in whom existing comorbidities would not preclude the expected benefit from reduction of the mitral regurgitation.

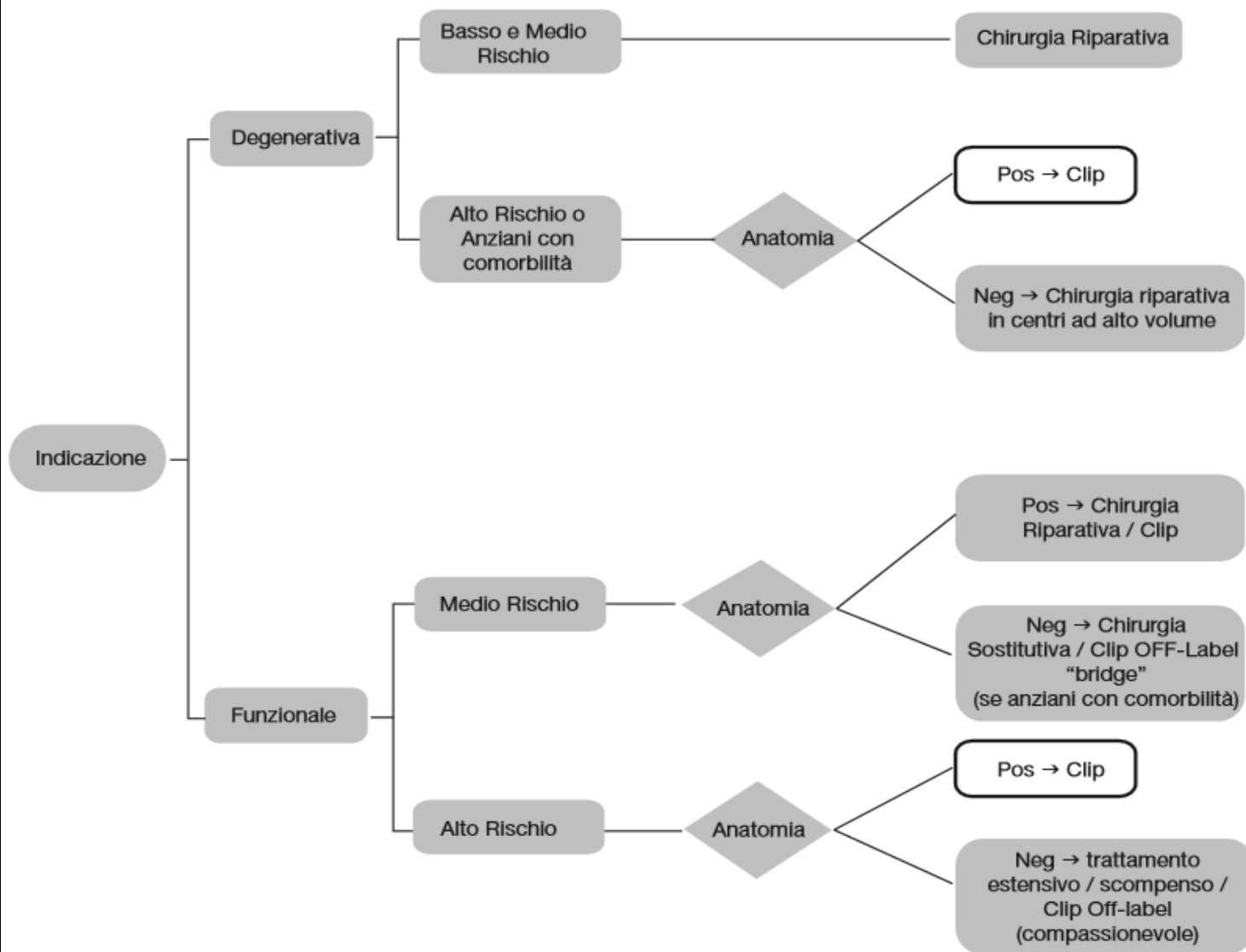
2.0 CONTRAINDICATIONS

The MitraClip® NT Clip Delivery System is contraindicated in DMR patients with the following conditions:

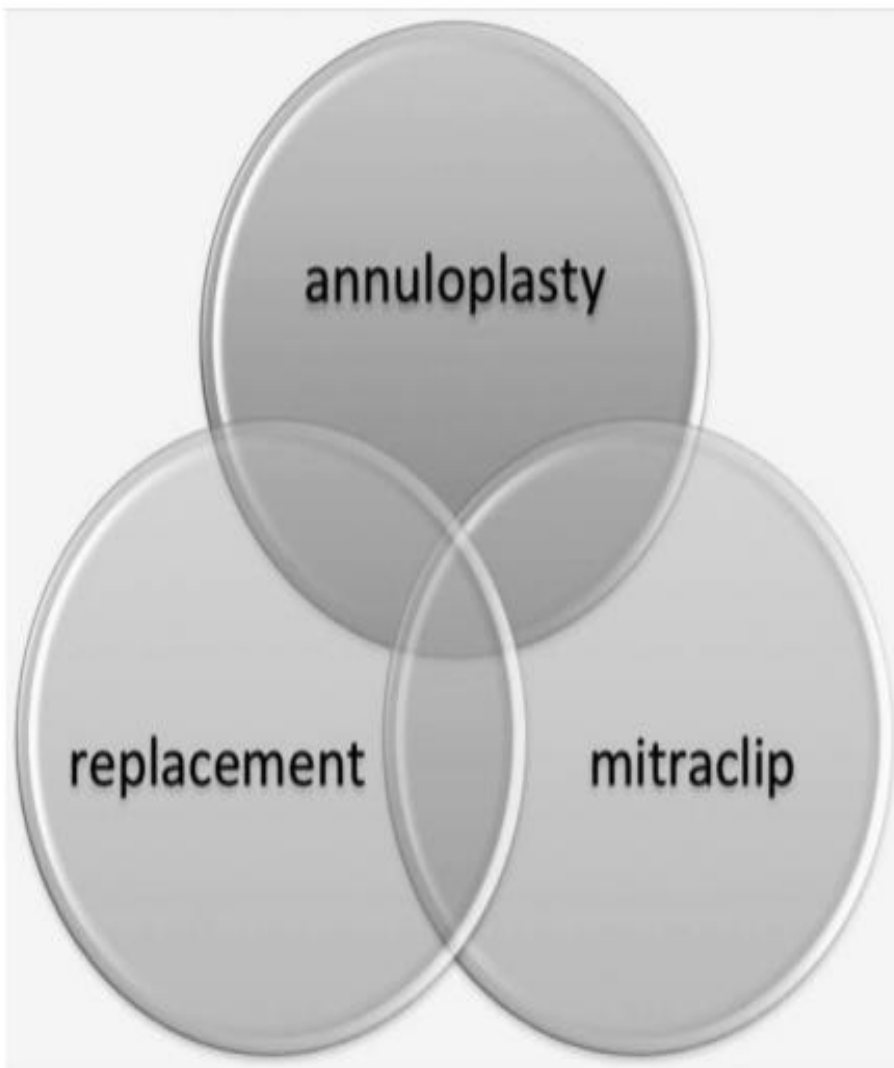
- Patients who cannot tolerate procedural anticoagulation or post procedural anti-platelet regimen
- Active endocarditis of the mitral valve
- Rheumatic mitral valve disease
- Evidence of intracardiac, inferior vena cava (IVC) or femoral venous thrombus

3.0 WARNINGS

- **DO NOT use MitraClip® NT outside of the labeled indication. Treatment of non-prohibitive risk DMR patients should be conducted in accordance with standard hospital practices for surgical repair and replacement.**
- MitraClip® NT is intended to reduce mitral regurgitation. The MitraClip® NT procedure is recommended to be performed when an experienced heart team has determined that reduction of MR to ≤ 2+ is reasonably expected following the MitraClip® NT. If MR reduction to ≤ 2+ is not achieved, the benefits of reduced symptoms and hospitalizations, improved quality of life, and reverse LV remodeling expected from MitraClip® NT may not occur.
- The MitraClip® NT Device should be implanted with sterile techniques using fluoroscopy and echocardiography (e.g., transesophageal [TEE] and transthoracic [TTE]) in a facility with on-site cardiac surgery and immediate access to a cardiac operating room.
- Read all instructions carefully. Failure to follow these instructions, warnings and precautions may lead to device damage, user injury or patient injury. Use universal precautions for biohazards and sharps while handling the MitraClip® NT System to avoid user injury.
- Use of the MitraClip® NT should be restricted to those physicians trained to perform invasive endovascular and transseptal procedures and those trained in the proper use of the system.
- The Clip Delivery System is provided sterile and designed for single use only. Cleaning, re-sterilization and / or reuse may result in infections, malfunction of the device or other serious injury or death.



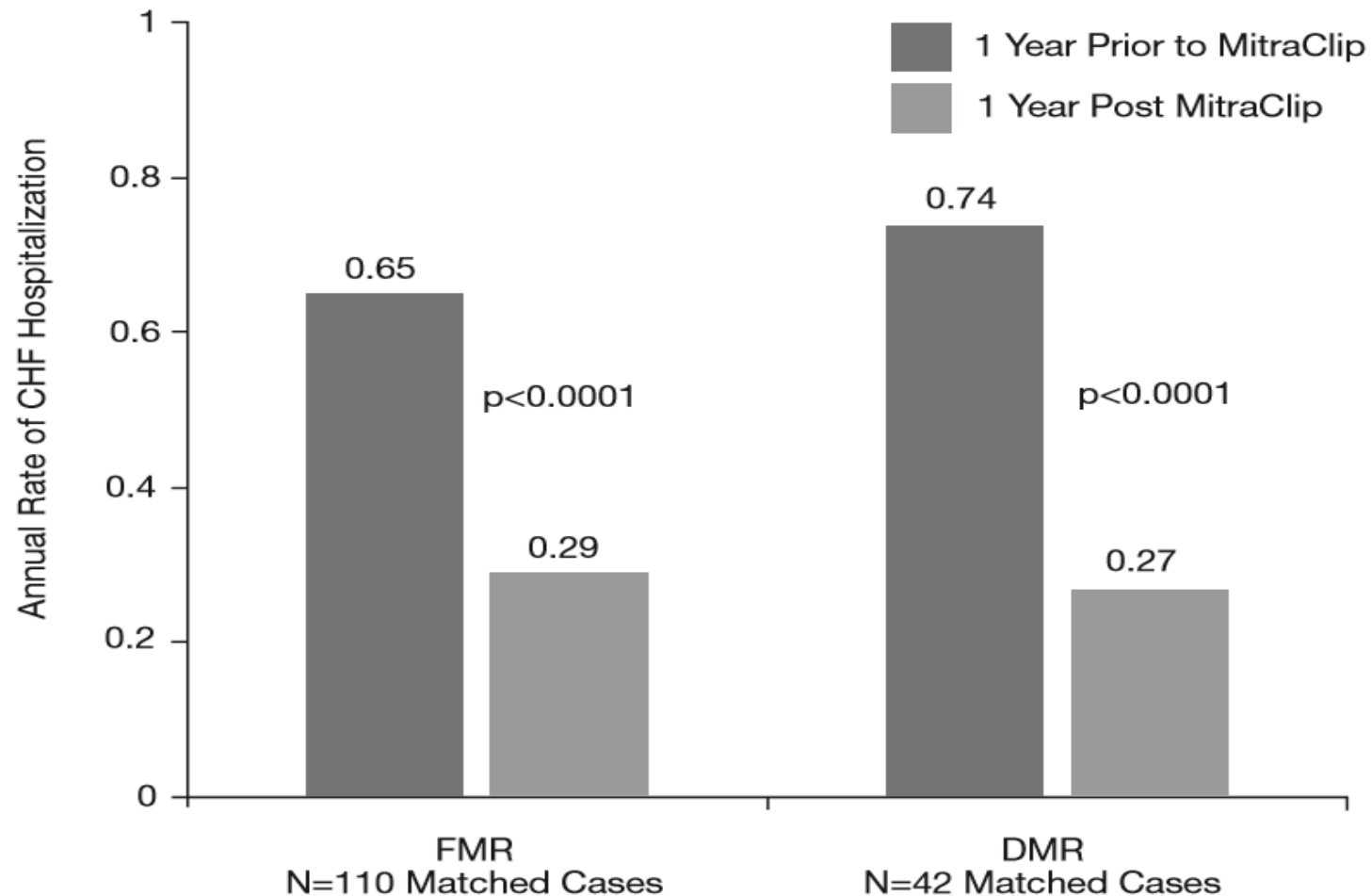
Algoritmo decisionale per il trattamento della patologia mitralica.



- **Annuloplastica:** insufficienza mitralica funzionale da dilatazione anulare e tethering simmetrico.
- **Stand-alone MitraClip:** insufficienza funzionale con tethering asimmetrico/ insufficienza degenerativa con minima dilatazione anulare.
- **Combinazione Annuloplastica + MitraClip:** Insufficienza degenerativa con importante dilatazione anulare/ Insufficienza funzionale avanzata.
- **Replacement:** insufficienza funzionale e degenerativa molto avanzata.

Complementarietà dei dispositivi per plastica/sostituzione mitralica percutanea.

Economic Value



Incidenza di (ri)ospedalizzazioni per scompenso cardiaco nei pazienti affetti sia da insufficienza mitralica degenerativa (DMR), sia funzionale (FMR=Functional Mitral Regurgitation) nell'anno precedente e successivo all'impianto di Mitraclip. Relazione dei dati del registro al alto rischio (High surgical risk study (HRR) registry). Whitlow, comunicazione presso il congresso dell'American College of Cardiology, 2012.

Table 2 – *Trials and registers currently published.*

	NYHA III-IV	Frazione d'eiezione del ventricolo sinistro	IM funzionale	Successo procedurale acuto	Mortalità/Sopravvivenza
EVEREST RCT N Engl J Med (2011)	52%	60%	27%	77%	Mortalità: 1% a 30 giorni; 6% a 12 mesi
TRAMI European Journal of Heart Failure (2012)	93%	FE < 50% nel 71% dei pazienti	71%	94%	Mortalità: 2,5% intra-ospedaliera; 12.5% post-dimissione*
GRASP Am J Cardiol (2013)	80%	38%	76%	100%	Mortalità: 0,9% a 30 giorni; 16.2% a 12 mesi [#]
FRENCH Arch Cardiovasc Dis. (2013)	81%	40%	73.8%	95.2%	Mortalità: 3.2% intra-ospedaliera Sopravvivenza a 6 mesi: 83.15%
ACCESS-Eu J Am Coll Cardiol (2013)	84.9%	FE ≤40% nel 52.3% dei pazienti	77.1%	99.6%	Mortalità: 3,4% a 30 giorni; Sopravvivenza 81.8% a 12 mesi
Mitra Swiss Open Heart (2014)	82%	48%	62%	85%	Sopravvivenza 96 % a 30 giorni Sopravvivenza 75% a 24 mesi

ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012

The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC

In patients with an indication for valve repair but judged inoperable or at unacceptably high surgical risk, percutaneous edge-to-edge repair may be considered in order to improve symptoms

Indicazioni per IM primaria

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Table 15. Indications for surgical aortic regurgitation

Class	Level of Evidence	Class	Level of Evidence
Class I	A	Class I	A
Class I	B	Class I	B
Class II	A	Class II	A
Class II	B	Class II	B
Class III	A	Class III	A
Class III	B	Class III	B

4.1.4 Percutaneous aortic regurgitation repair
 Percutaneous aortic regurgitation repair (PAR) is a minimally invasive approach to aortic regurgitation repair. PAR is performed using a transcatheter approach through the femoral artery. PAR is performed using a transcatheter approach through the femoral artery. PAR is performed using a transcatheter approach through the femoral artery.

4.1.5 Indications for intervention
 Surgical aortic regurgitation repair is indicated in patients with aortic regurgitation who are symptomatic and have aortic regurgitation severity of grade 3 or 4. Surgical aortic regurgitation repair is indicated in patients with aortic regurgitation severity of grade 3 or 4.

4.1.6 Indications for intervention
 Percutaneous aortic regurgitation repair is indicated in patients with aortic regurgitation who are symptomatic and have aortic regurgitation severity of grade 3 or 4. Percutaneous aortic regurgitation repair is indicated in patients with aortic regurgitation severity of grade 3 or 4.

4.1.7 Indications for intervention
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“La procedura percutanea edge-to-edge può essere presa in considerazione in pazienti sintomatici con severa insufficienza mitralica primaria che rispondono ai criteri di eleggibilità, sono giudicati inoperabili o ad alto rischio chirurgico da un ‘heart team’, e hanno un’aspettativa di vita maggiore di 1 anno (classe di raccomandazione IIb, livello di evidenza C)”

Indicazioni per IM secondaria

4.2.1 Mitral regurgitation
 Mitral regurgitation (MR) is a common valvular disease. Mitral regurgitation is a common valvular disease. Mitral regurgitation is a common valvular disease. Mitral regurgitation is a common valvular disease.

4.2.2 Mitral regurgitation
 Mitral regurgitation (MR) is a common valvular disease. Mitral regurgitation is a common valvular disease. Mitral regurgitation is a common valvular disease. Mitral regurgitation is a common valvular disease.

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“La procedura percutanea MitraClip può essere presa in considerazione in pazienti sintomatici con severa insufficienza mitralica secondaria nonostante ottima terapia medica (incluso la CRT se indicato), che rispondono ai criteri di eleggibilità, sono giudicati inoperabili o ad alto rischio chirurgico da un team di cardiologi e cardiochirurghi”, e hanno un’aspettativa di vita maggiore di 1 anno (classe di raccomandazione IIb, livello di evidenza C)”

European Heart Journal
 ESC/EACTS GUIDELINES

Guidelines on the management of valvular heart disease (version 2012)

The Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

Authors/Task Force Members: Alec Vahanian (Chairperson) (France), Ottavio Alfieri (Chairperson) (Italy), Felicia Andreotti (Italy), Manuel J. Antunes (Portugal), Gonzalo Barón-Esquivias (Spain), Helmut Baumgartner (Germany), Michael Andrew Borger (Germany), Thierry P. Carrel (Switzerland), Michele De Bonis (Italy), Arturo Evangelista (Spain), Volker Falk (Switzerland), Bernard Jung (France), Patrizio Lancellotti (Belgium), Luc Pierard (Belgium), Susanna Price (UK), Hans-Joachim Schäfers (Germany), Gerhard Schöfer (Germany), Janina Stepinska (Poland), Karl Swedberg (Sweden), Johanna Takkenberg (The Netherlands), Ulrich Otto Von Oppell (UK), Stephan Windecker (Switzerland), Jose Luis Zamorano (Spain), Marian Zembala (Poland)

PRACTICE GUIDELINE

2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: Executive Summary



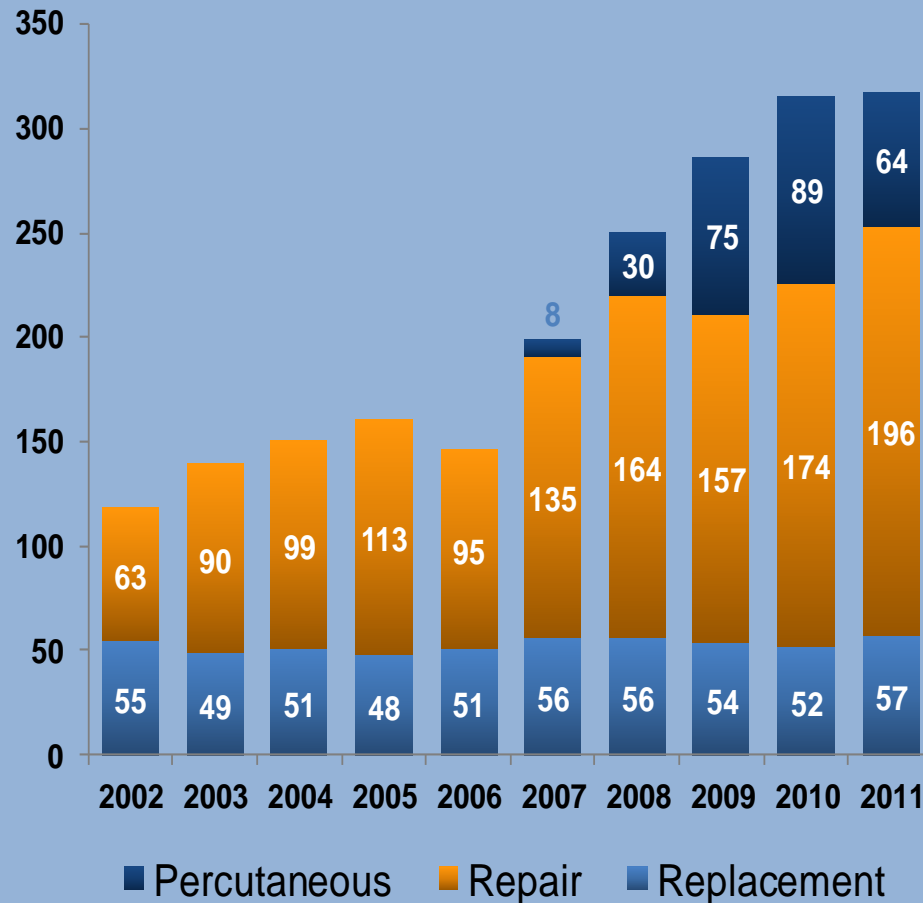
A Report of the American College of Cardiology/American Heart Association
Task Force on Practice Guidelines

*Developed in Collaboration With the American Association for Thoracic Surgery,
American Society of Echocardiography, Society for Cardiovascular Angiography and Interventions,
Society of Cardiovascular Anesthesiologists, and Society of Thoracic Surgeons*

Transcatheter MV repair may be considered for severely symptomatic patients (NYHA class III/IV) with chronic severe primary MR (stage D) who have a reasonable life expectancy but a prohibitive surgical risk because of severe comorbidities (IIb – B)

Percutaneous Mitral Valve Repair is an Important Part of a Comprehensive Valve Center Serving Patients

Case study: Patient volume increases after introduction of MitraClip therapy




Multi-disciplinary Team

Bridging Traditional Silos


Collaboration across specialties is critical to MitraClip Therapy Success



Hospital Administrator



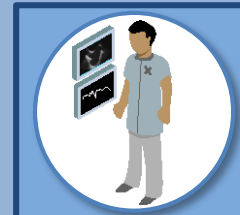
Heart Failure Specialist




Cardiac Surgery



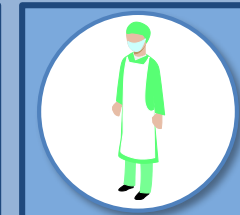
Interventional Cardiology



Echo Cardiology



Anesthesiology



Nursing / Cath-Lab Staff

Collaboration Required for:

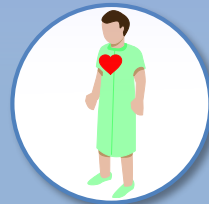
Patient Referral

Optimal Patient Selection

Plan Therapy & Resources

Echo Guidance & Communication

Post Procedure Care



Optimal Patient Care

Conclusioni

- Il trattamento chirurgico rimane il gold standard di riferimento per la terapia del rigurgito mitralico.
- La MitraClip è una tecnica sicura ed efficace, riducendo il rigurgito mitralico a meno di moderato.
- Il trattamento con MitraClip dovrebbe essere riservato ai pazienti affetti da insufficienza mitralica, sintomatici e non responsivi alla sola terapia medica, considerati ad alto rischio chirurgico, anziani con importanti comorbidità od inoperabili, con caratteristiche anatomiche adeguate alla riparazione con dispositivo MitraClip.
- Queste indicazioni sono in accordo con quelle recentemente sottolineate dalle linee guida della Società Europea di Cardiologia e della Società Americana. Rimaniamo in attesa dei risultati degli studi randomizzati per eventualmente estendere o circoscrivere l'indicazione.

CHIRURGIA MITRALICA vs. MITRACLIP



A circa 3 ore dall'inizio dell'intervento....



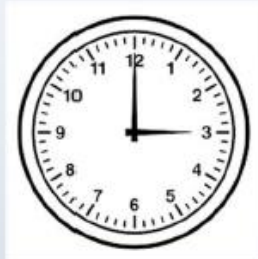
Sala operatoria di Cardiochirurgia



Laboratorio di Emodinamica



CHIRURGIA MITRALICA vs. MITRACLIP



Tra qualche anno....



Laboratorio di Emodinamica



Sala operatoria di Cardiochirurgia

