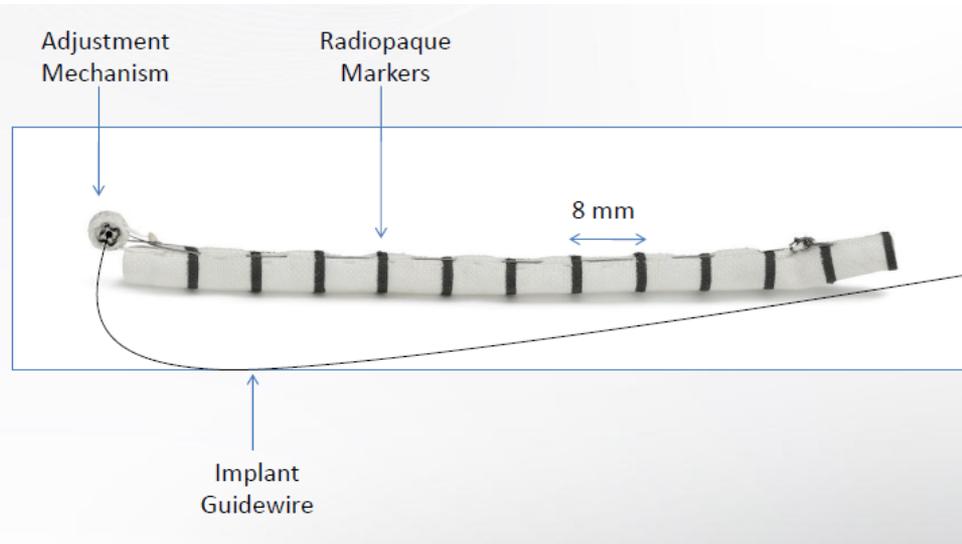
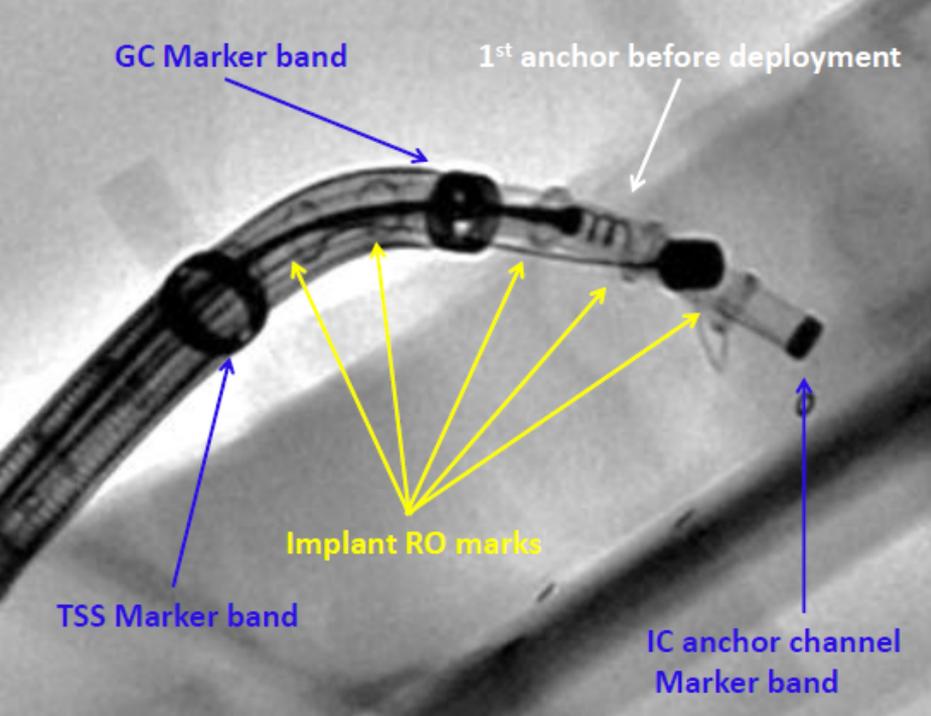


Annuloplastie percutanée

Cardioband

**Reproduire en percutané le
geste chirurgical
= Annuloplastie percutanée
directe**

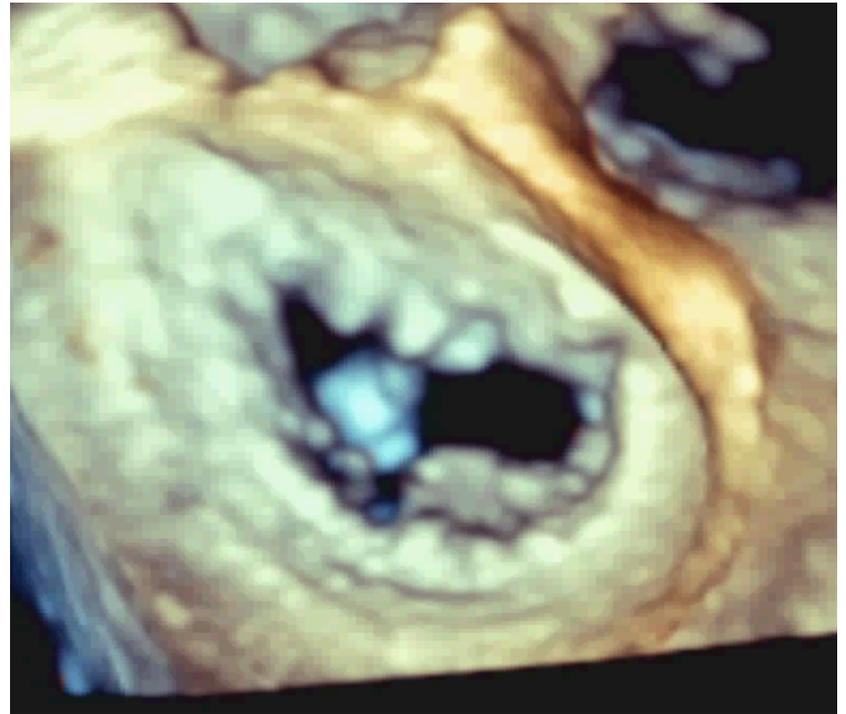


La procédure

AG - Guidage

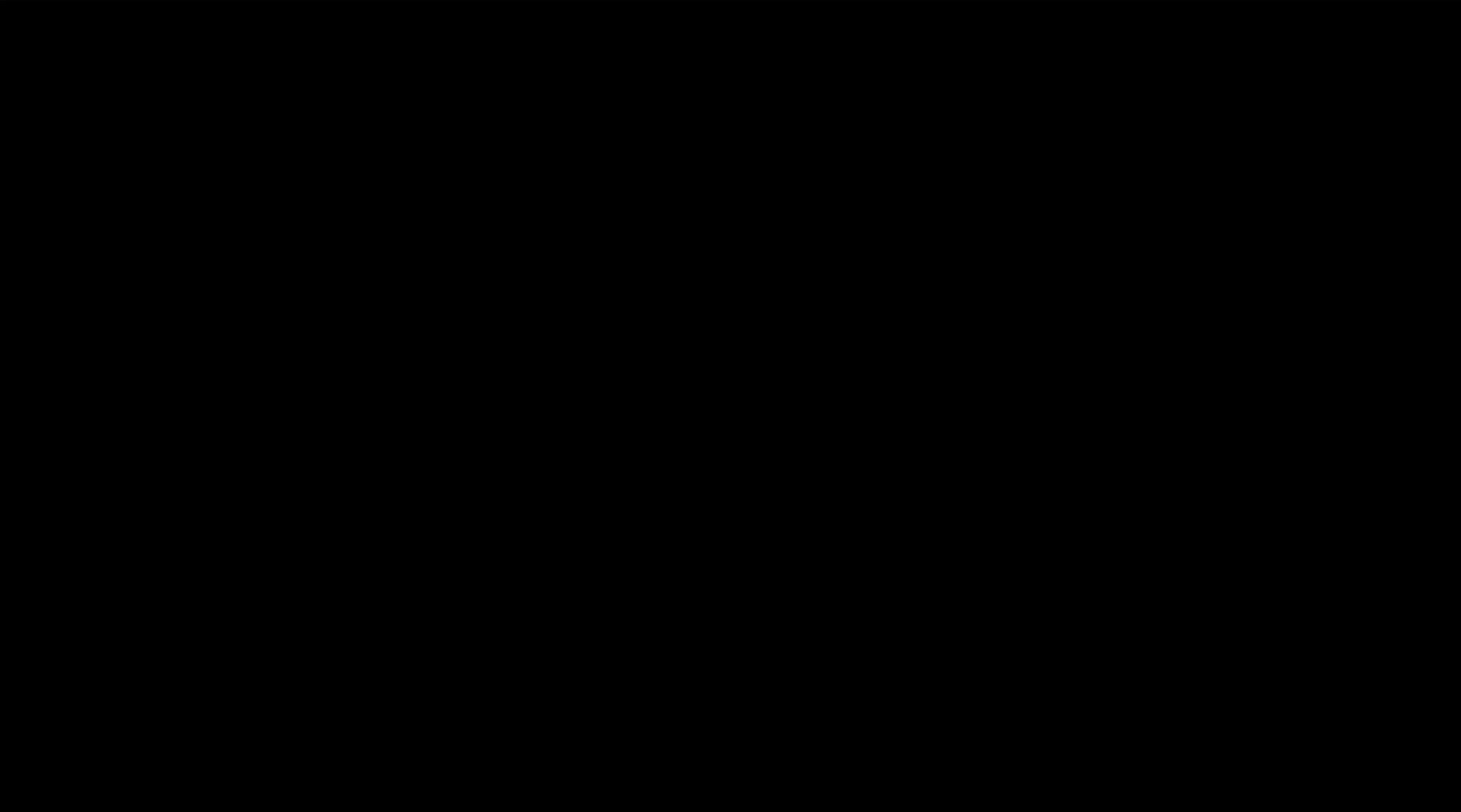


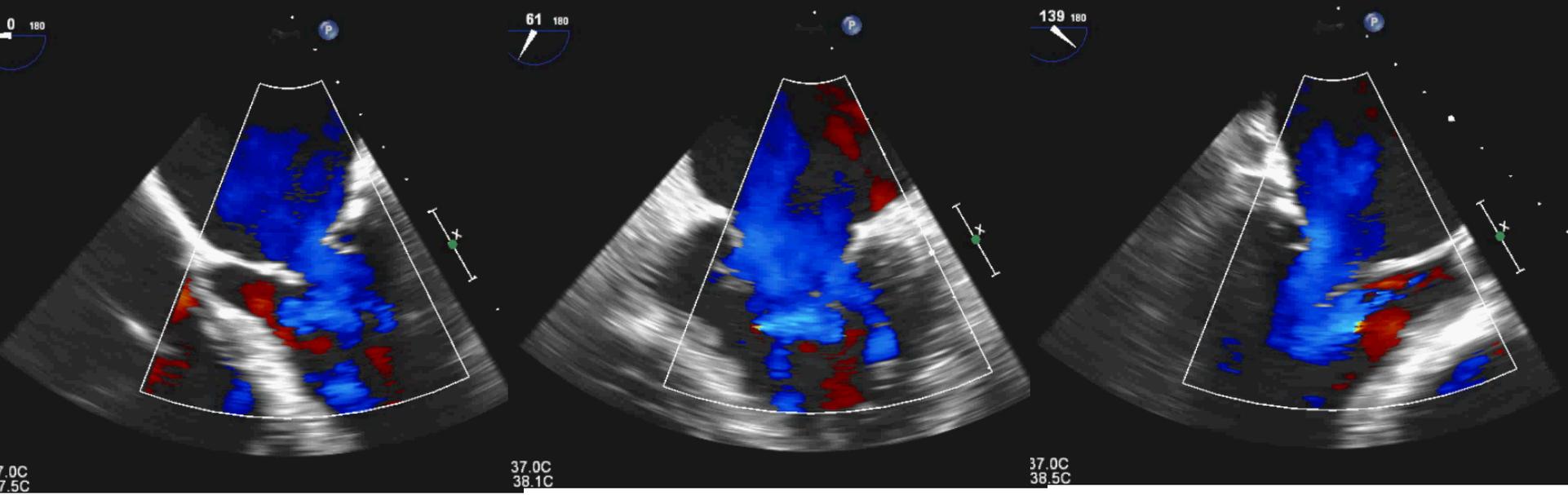
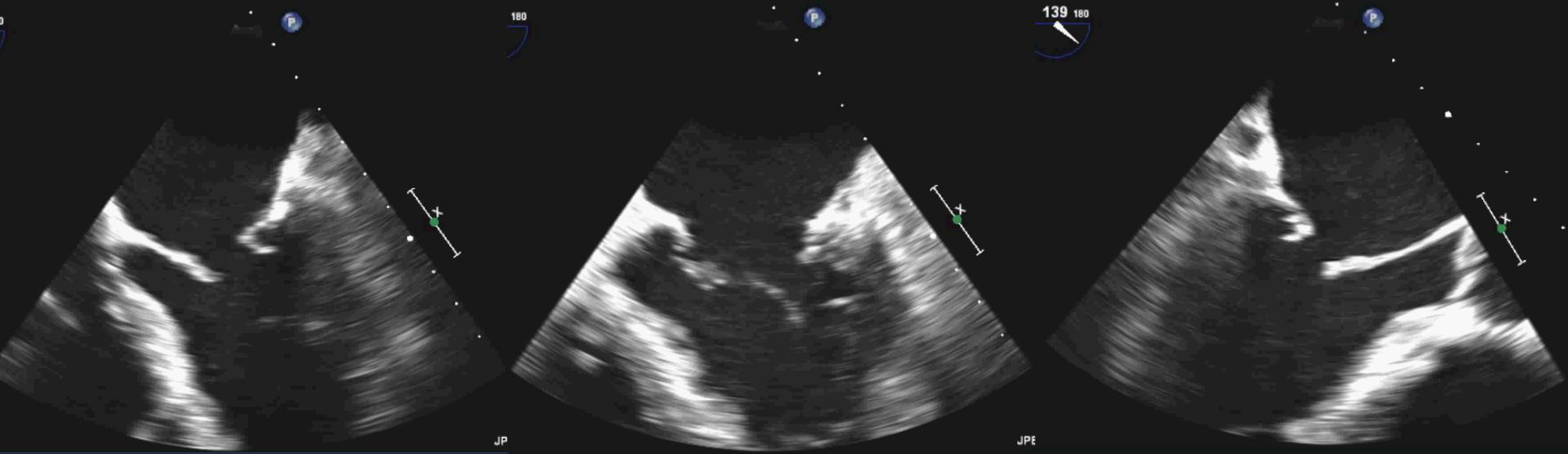
Fluoroscopie



ETO 2D et 3D

Live case

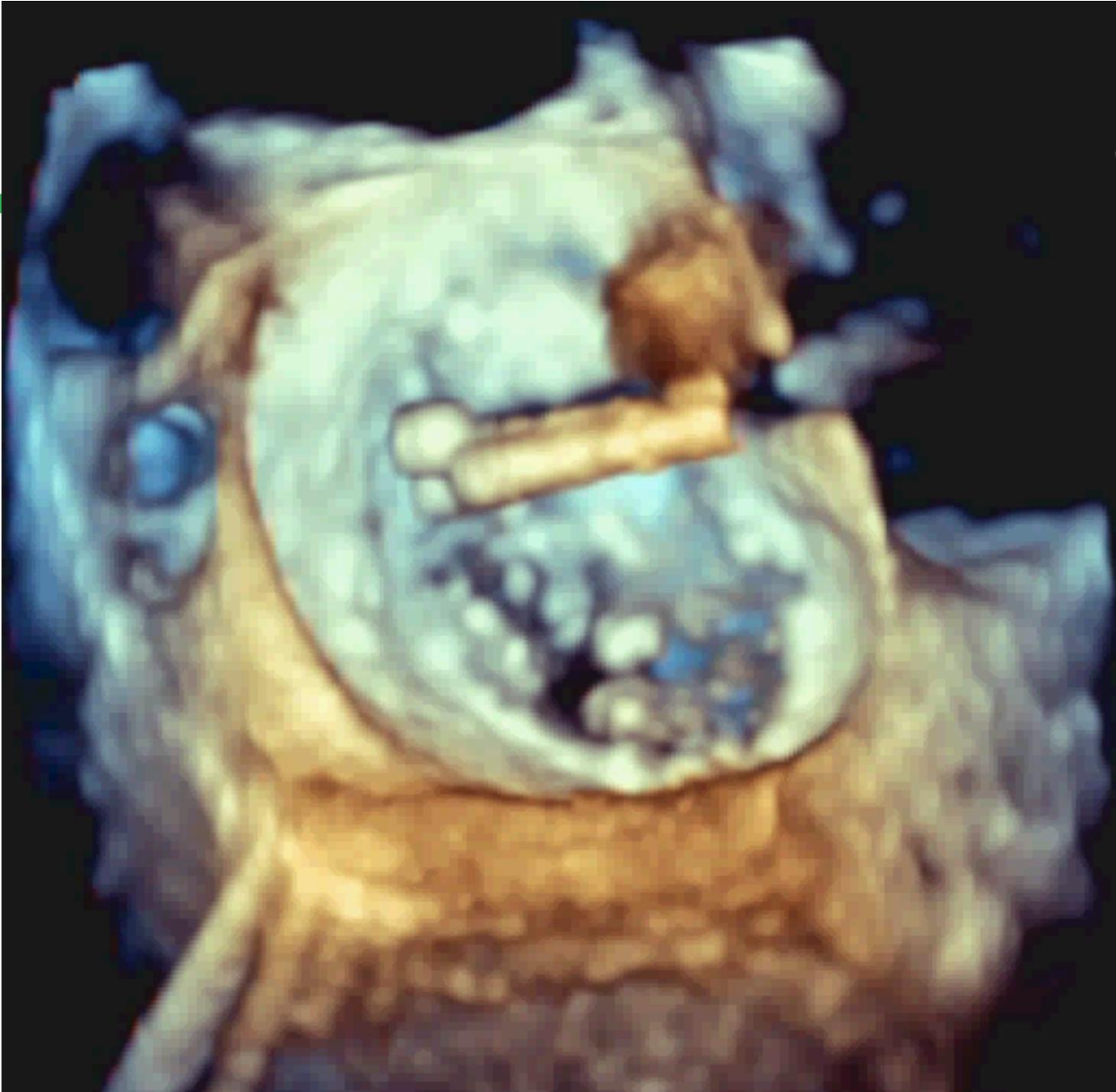


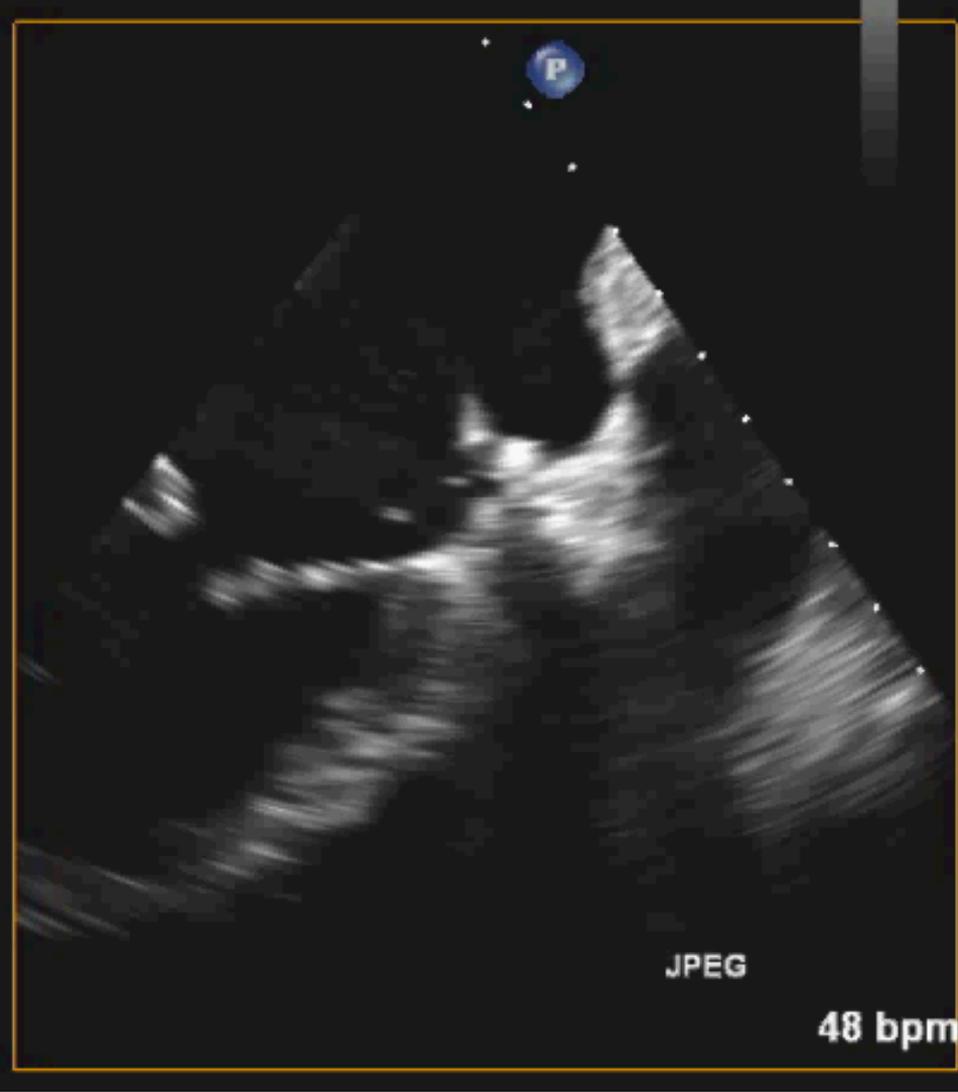
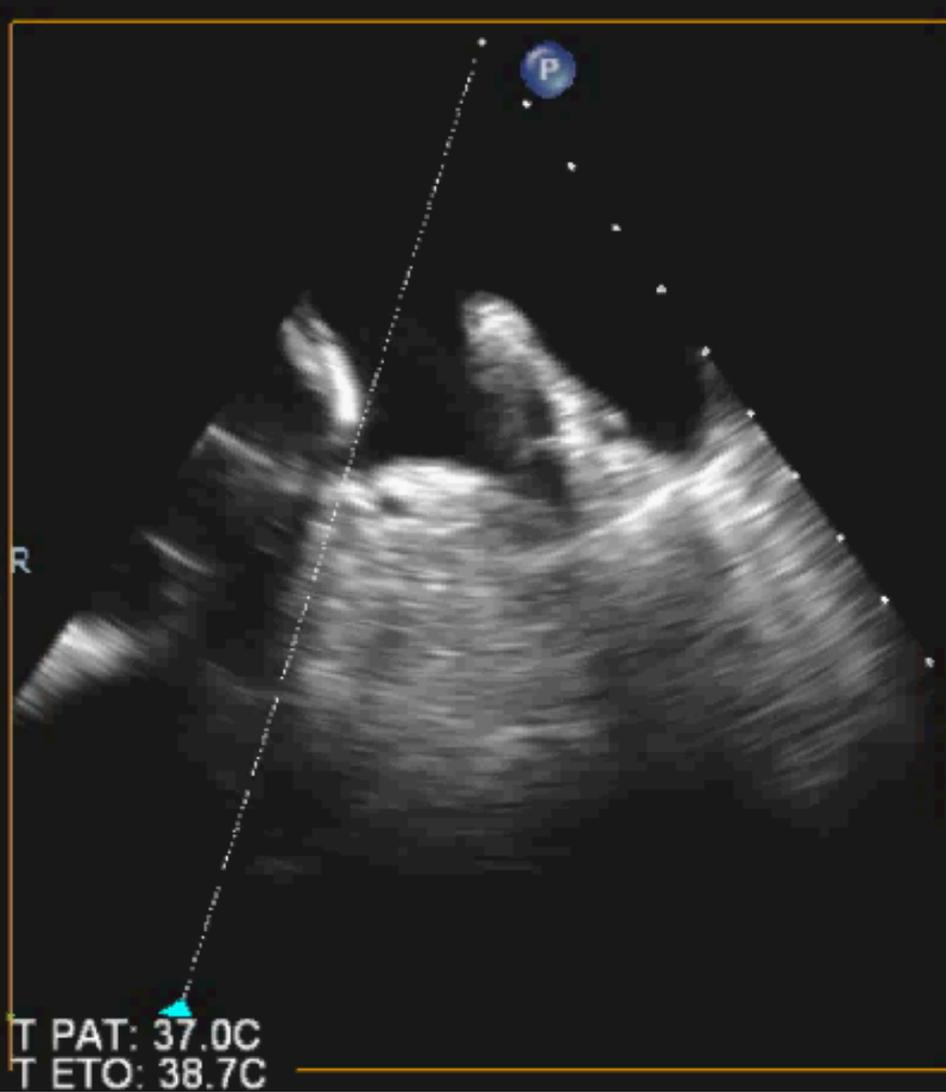


7.0C
7.5C

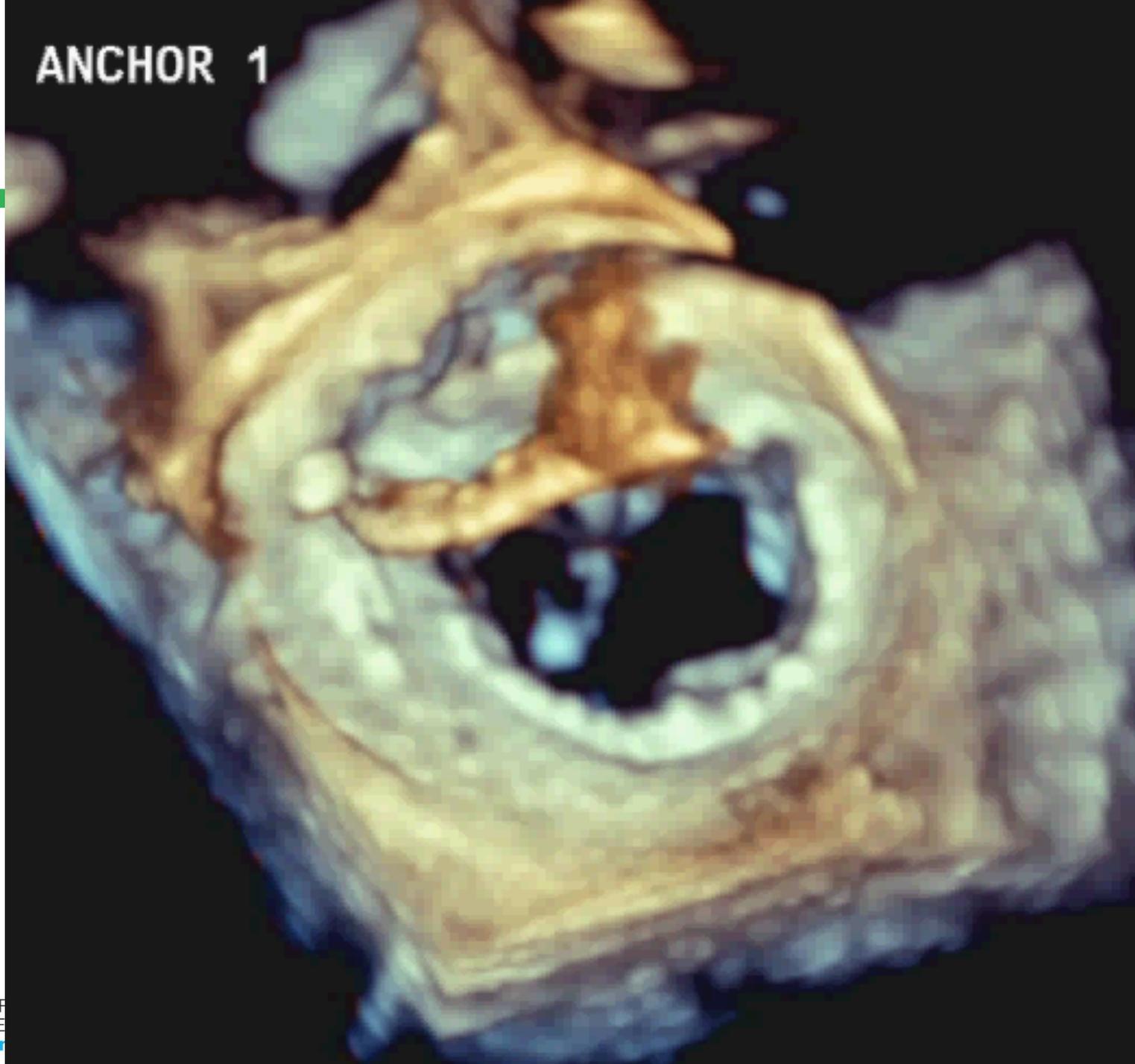
37.0C
38.1C

37.0C
38.5C

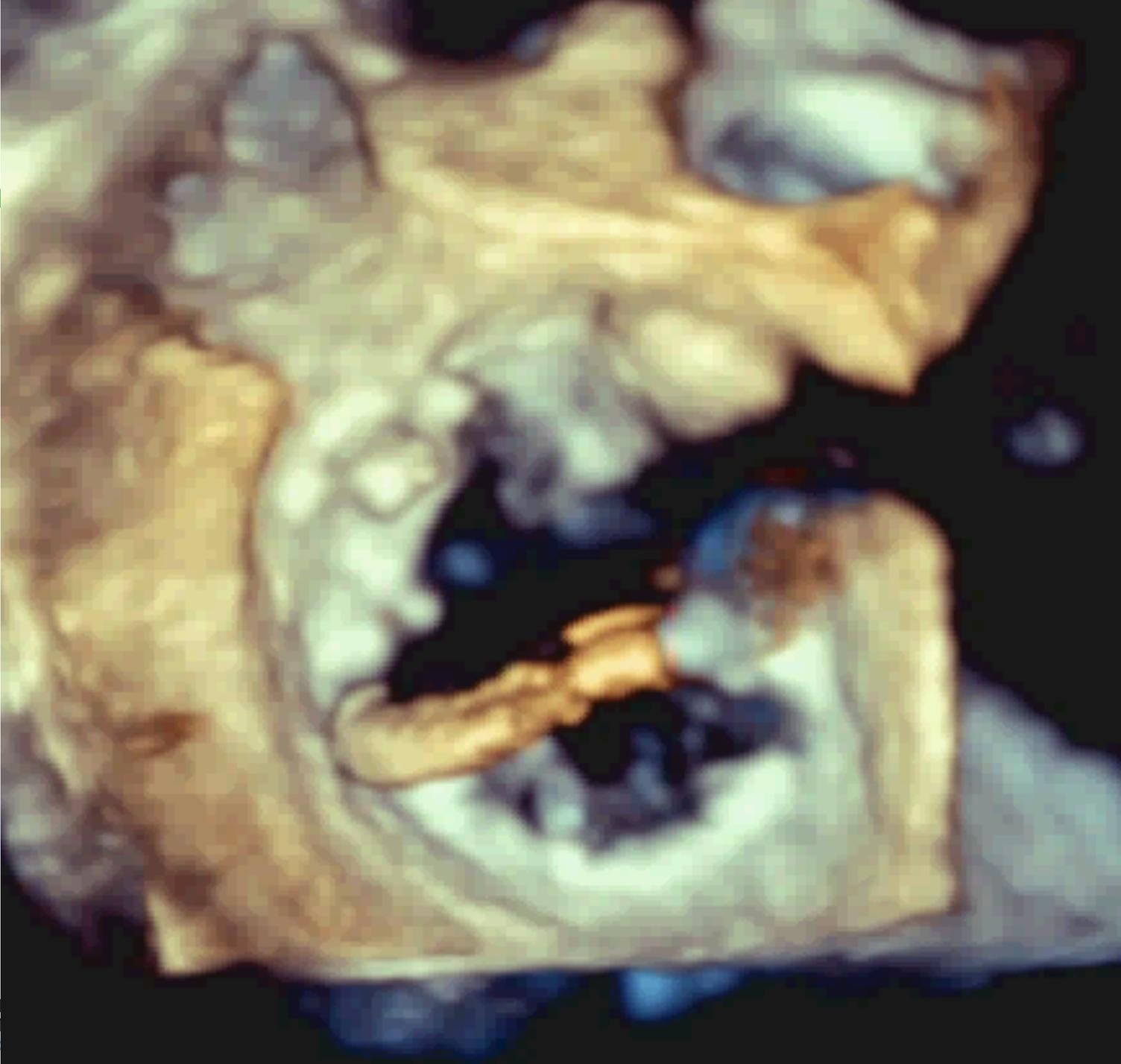




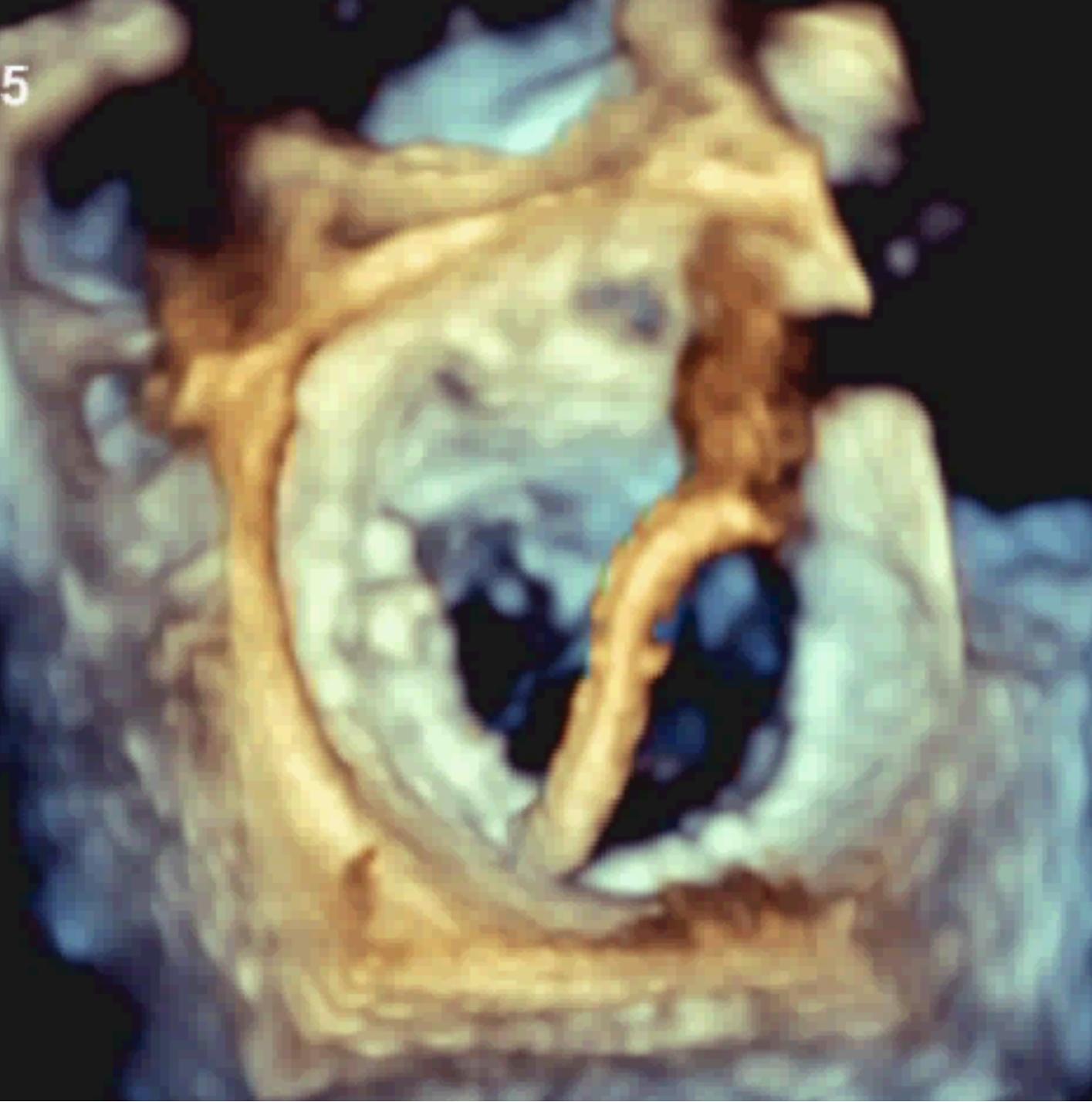
ANCHOR 1

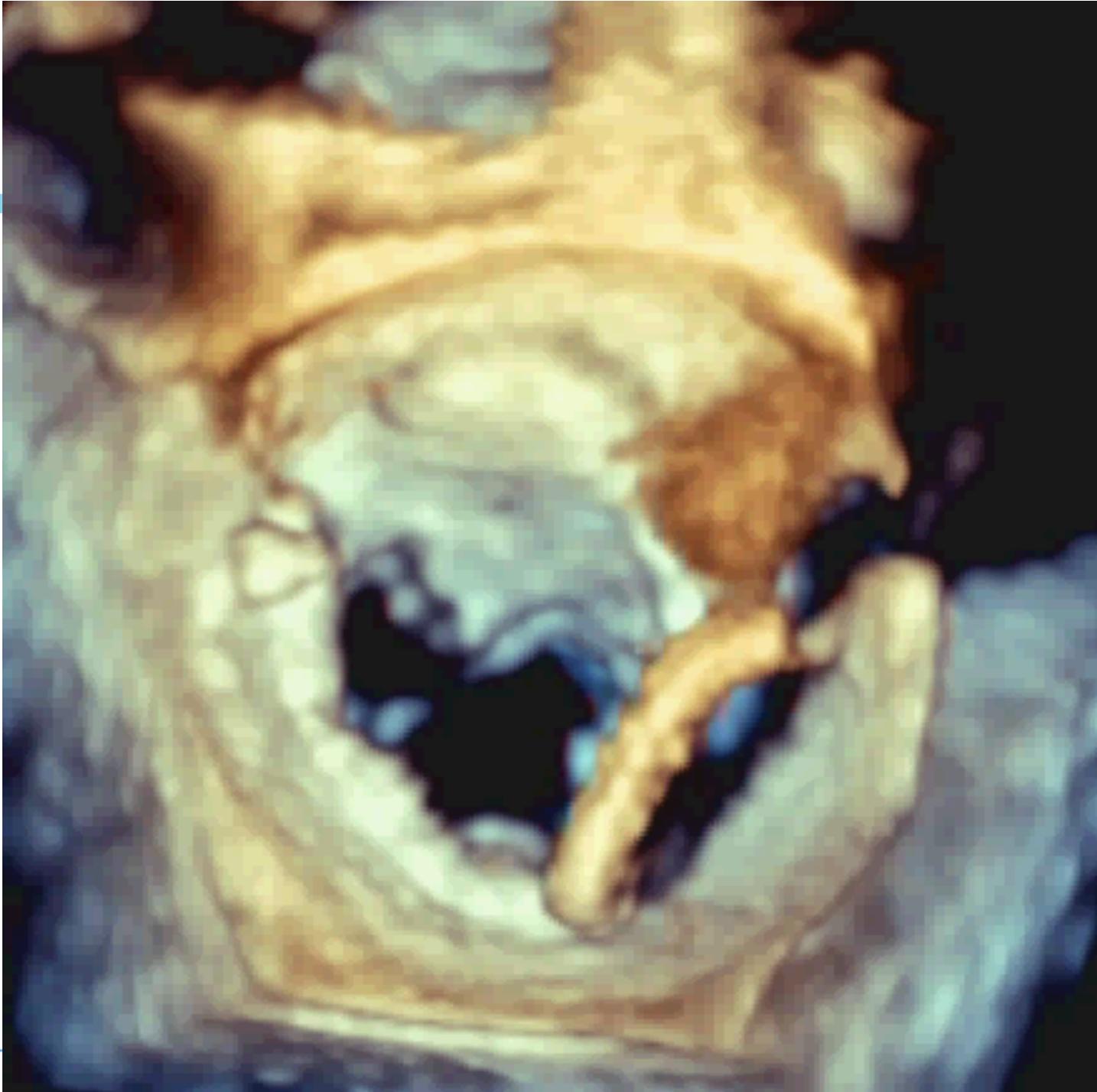




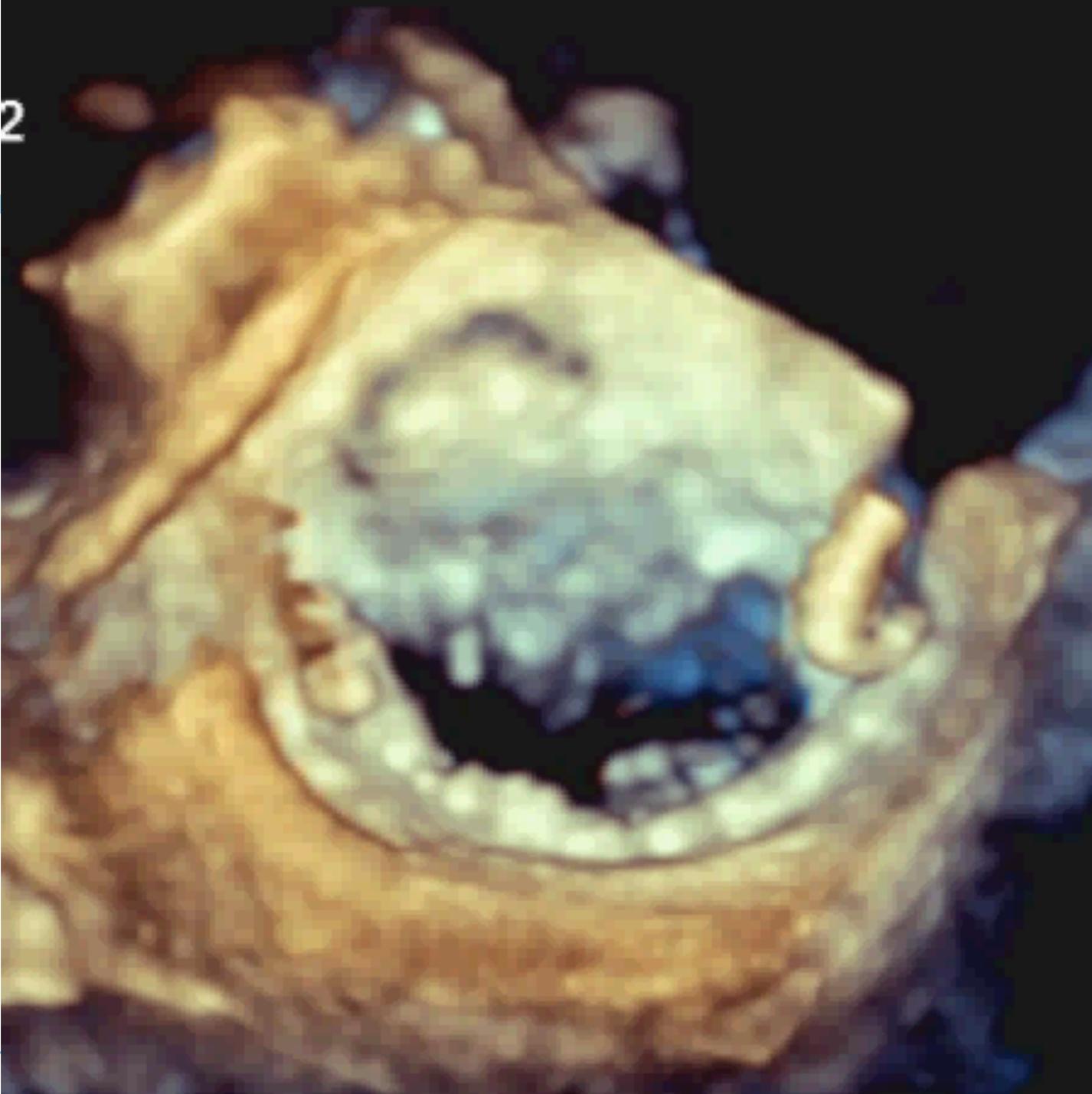


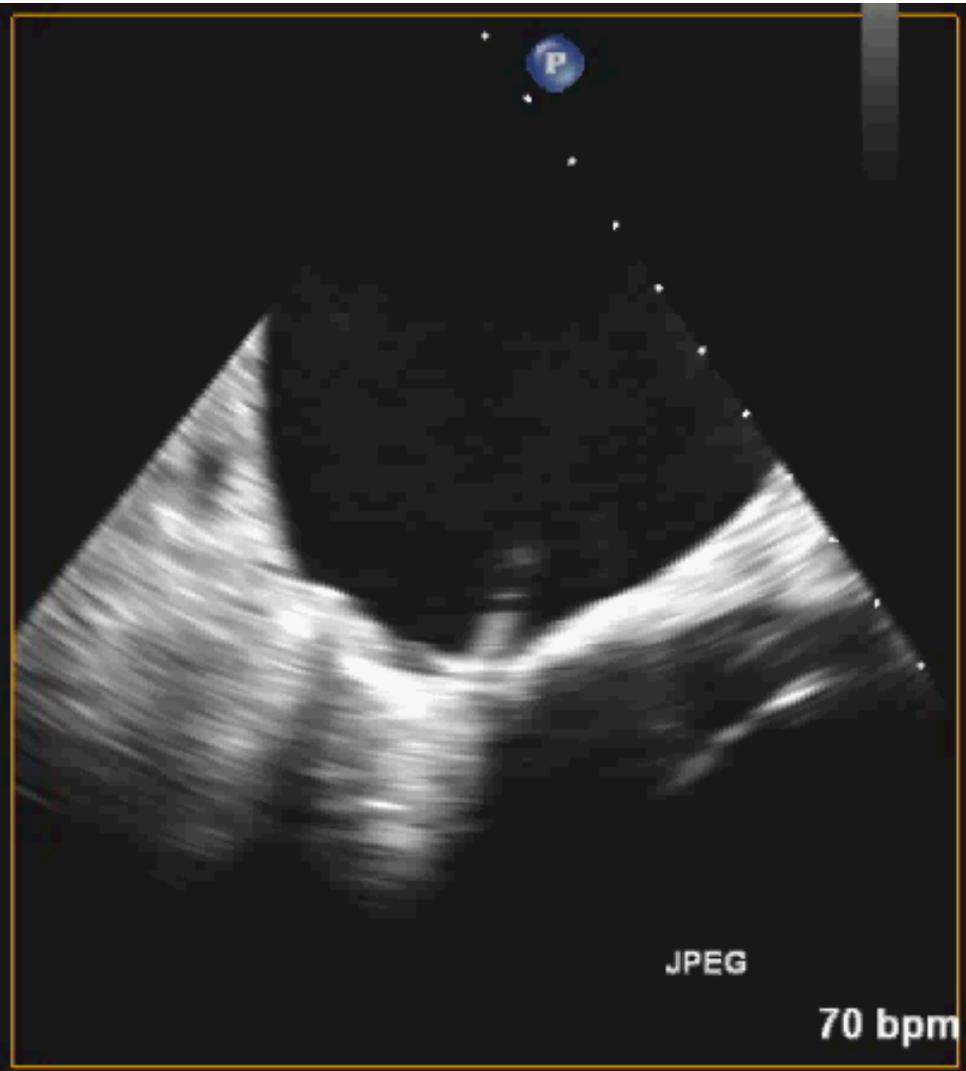
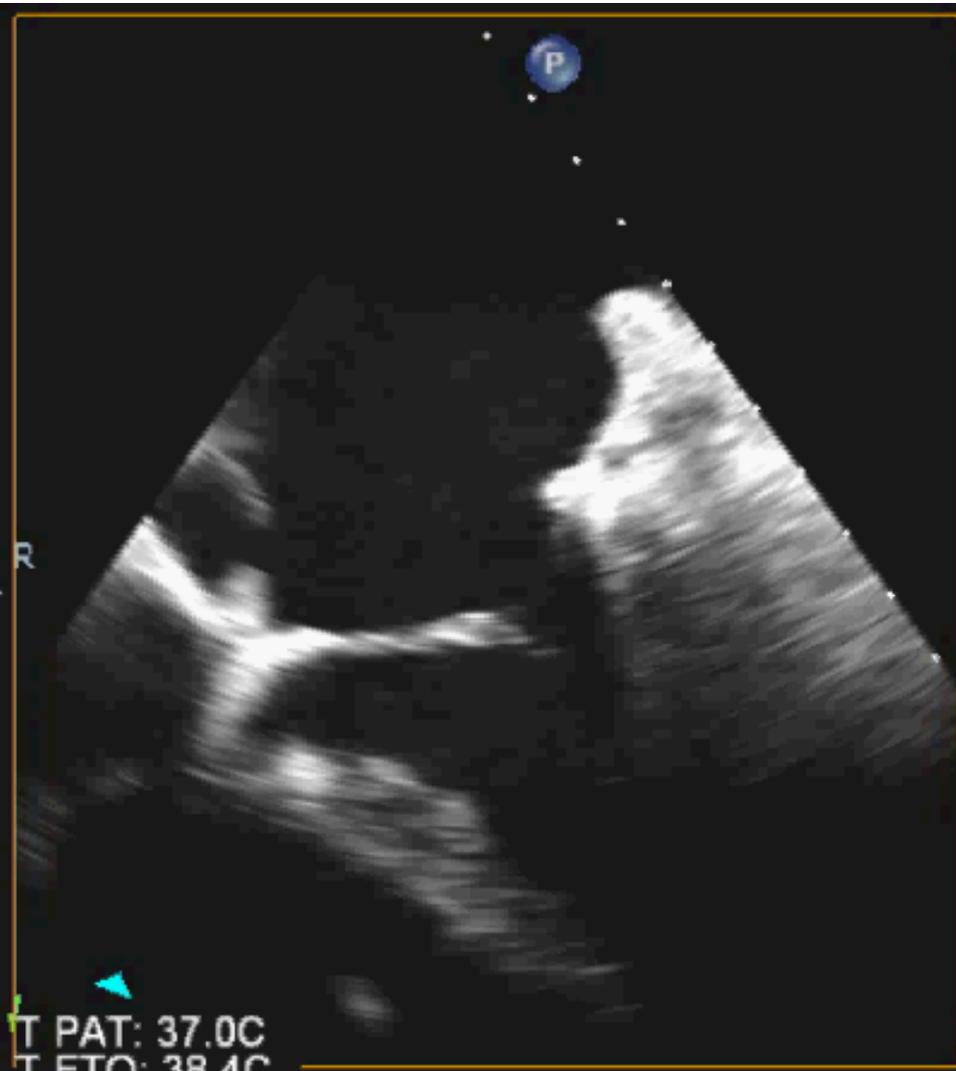
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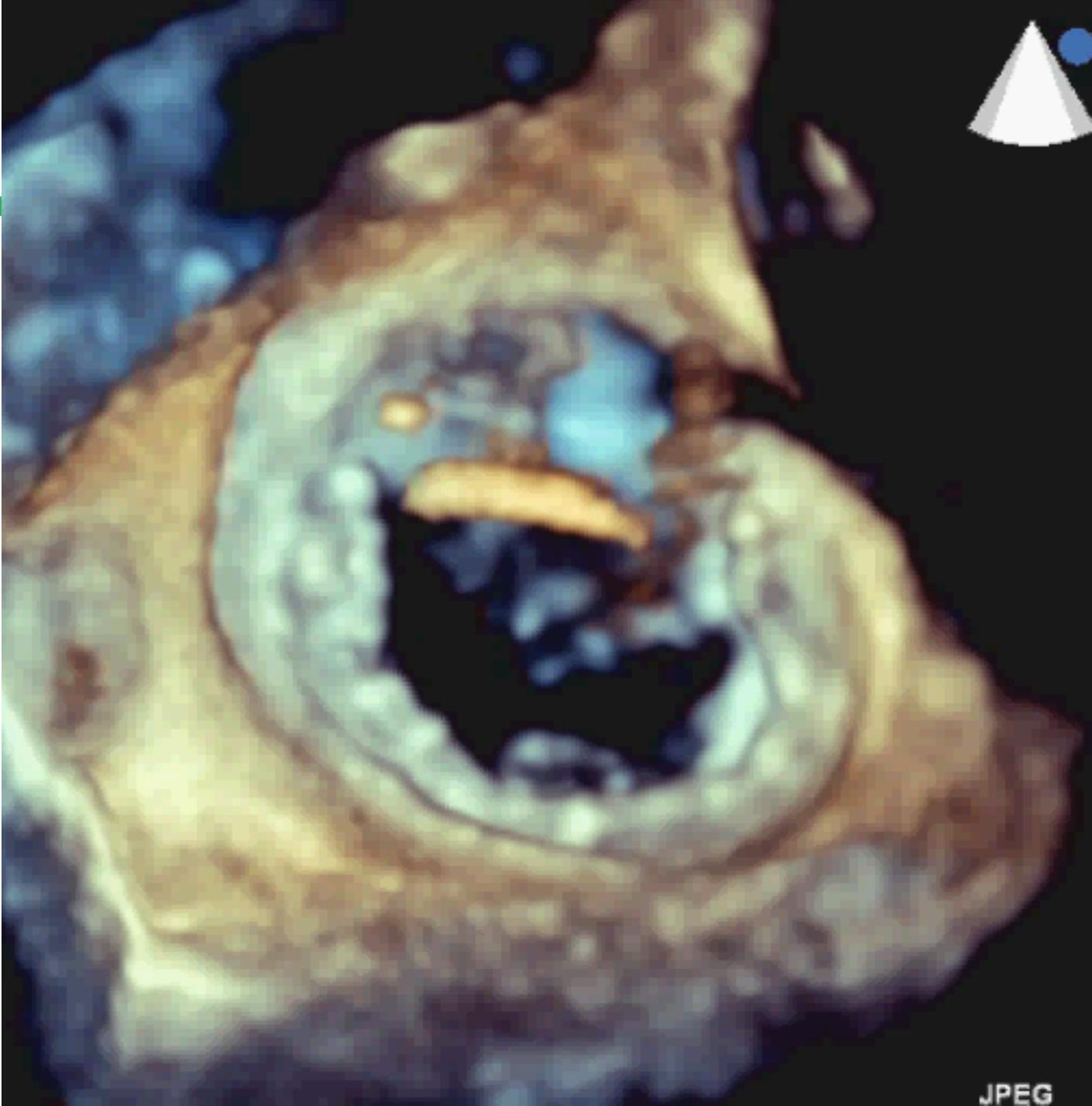


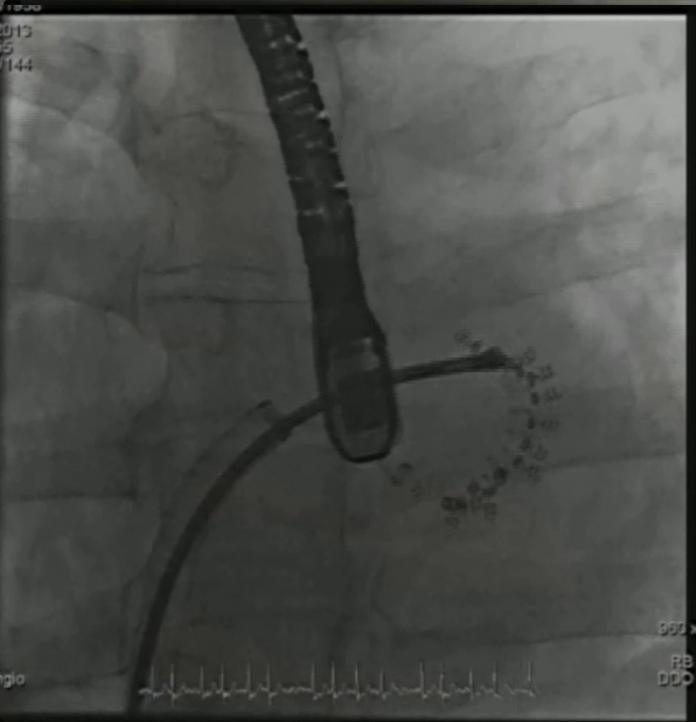


2











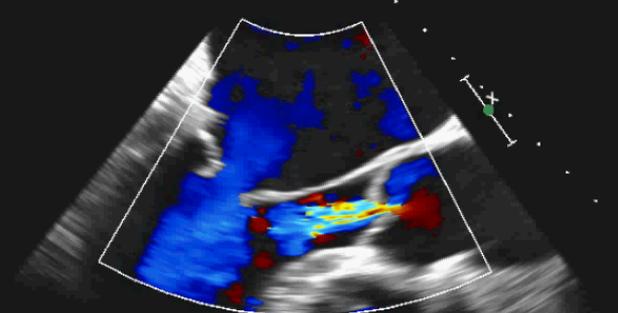
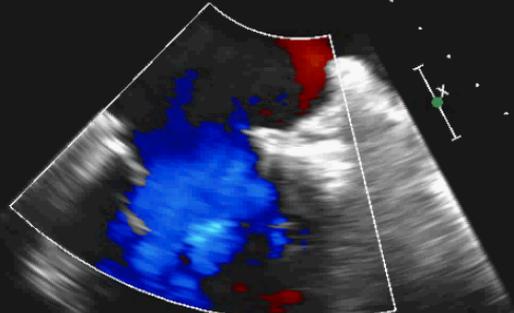
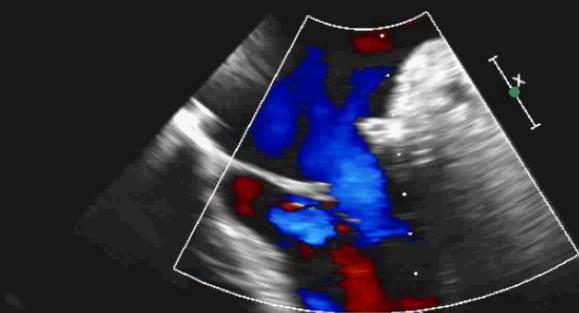
BEFORE CINCHING



BEFORE CINCHING



BEFORE CINCHING



37.0C
38.7C

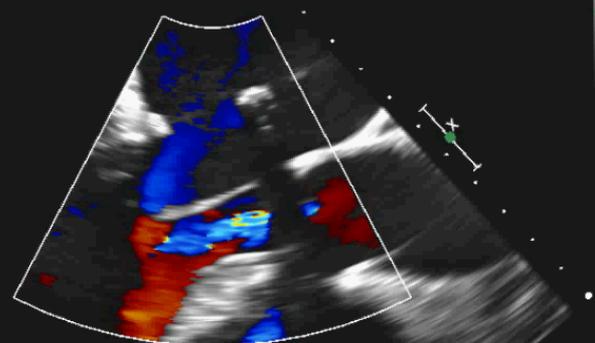
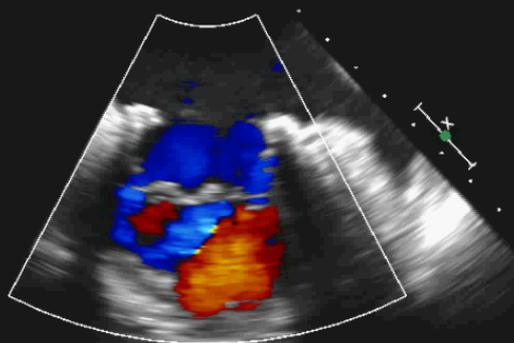
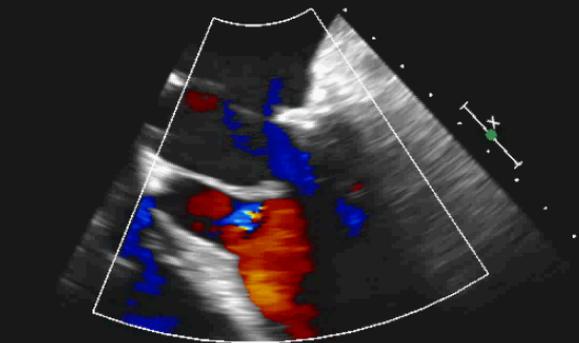
PAT: 37.0C
FTO: 38.2C

0C
7C

CINCHING 5

CINCHING 5

CINCHING 5



JPEG

70

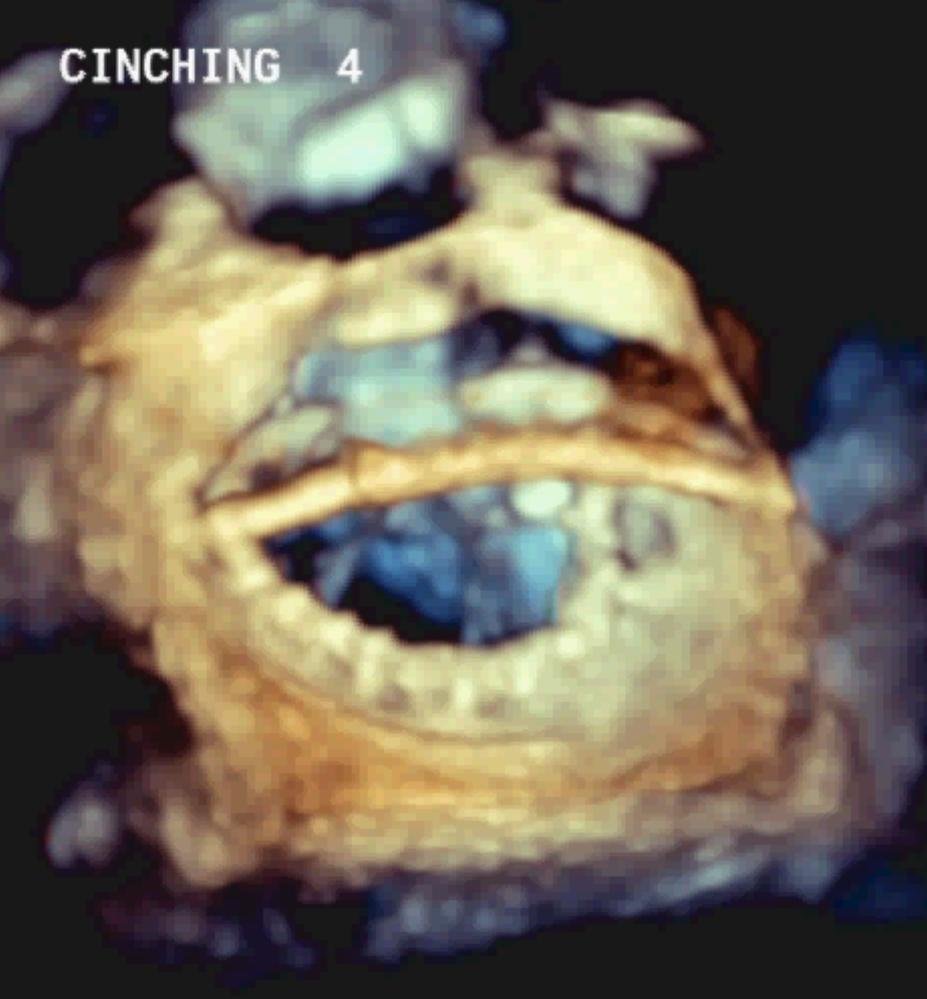
JPEG

7

JPEG

70

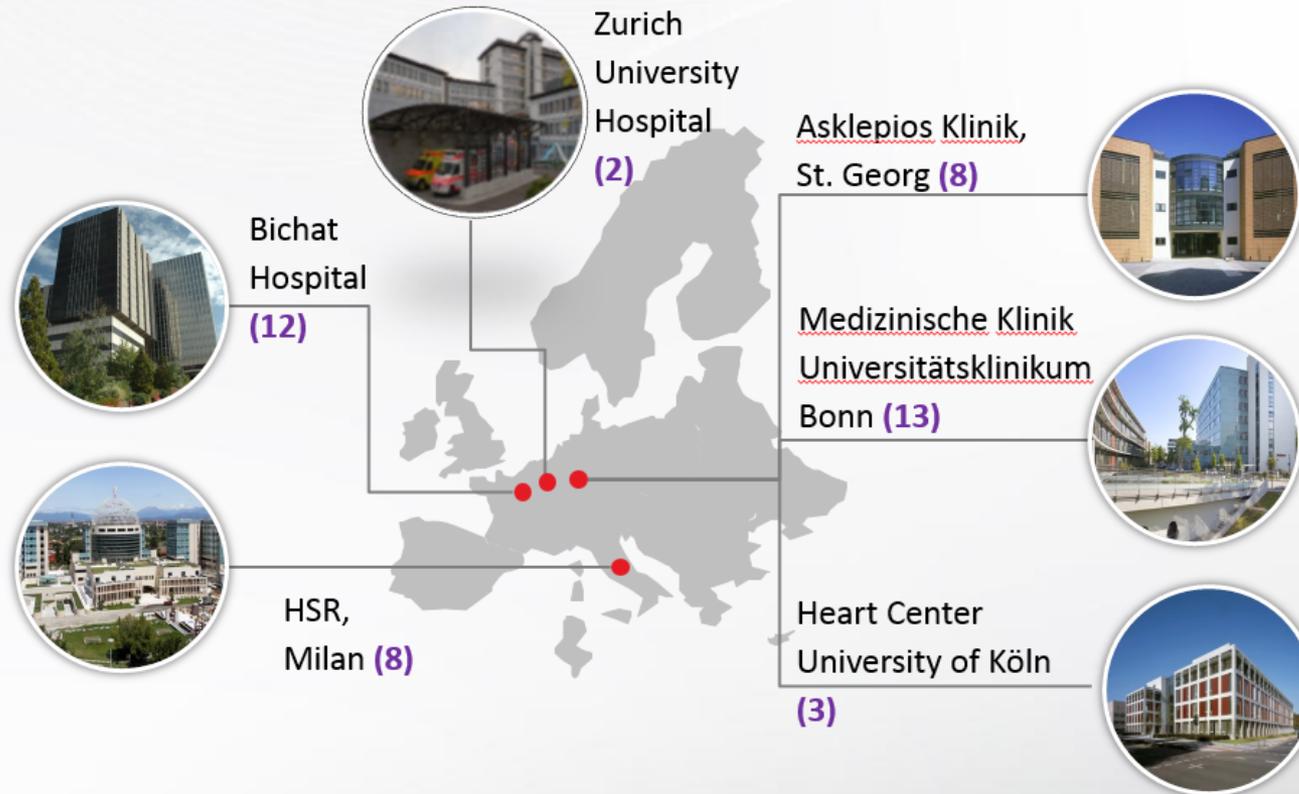
CINCHING 4



THE END



Les centres participants



***All Sites Implant Guided By Product Specialist Only.
3 More Sites Are Trained And Awaiting First Patient***

Population (N=45)

Variable

No. (%) or Mean_

Age (years)	71 (49-81)
Female Gender (%)	11 (24)
Euroscore II (%)	7
Baseline NYHA Class of III or IV (%)	87
Ischemic	28 (62)
Non Ischemic	17
LVEDD (mm) Avg (min-max)	61 (43-75)
LVEF (%) Avg (min-max)	32 (15-59)
Previous CABG	14 (31%)
COPD	9 (20%)
Moderate to Severe Renal Failure	31 (69%)
Severe Pulmonary Hypertension	8 (18%)
Atrial Fibrillation	36 (80%)

Résultats immédiats

- **Implantation du système
Cardioband : 100%**
- **Réduction de la fuite intra-
procédurale : 96%**

Sécurité à 30 jours

30 Day Events*

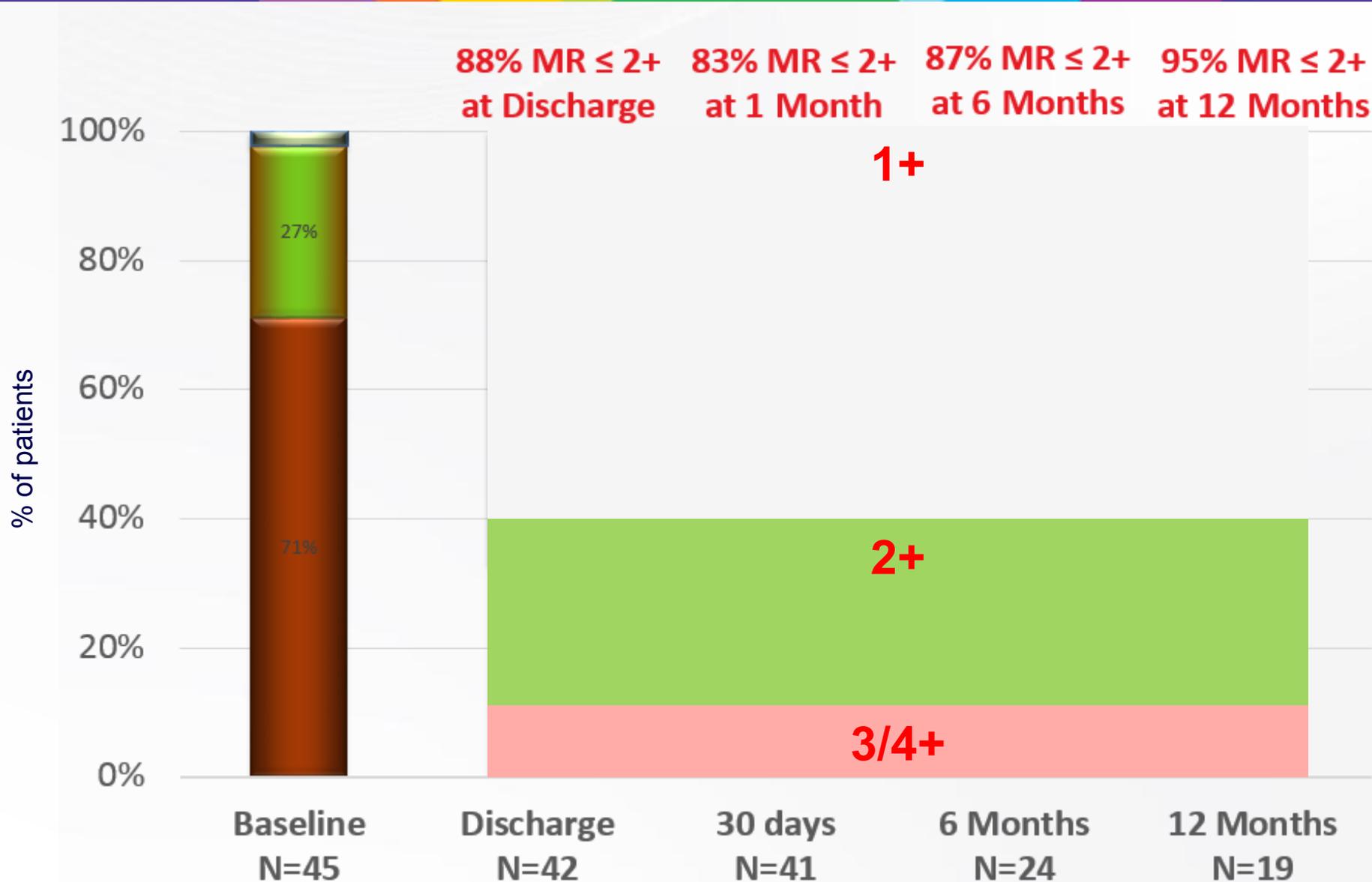
Patients Experiencing Event All Patients N=45

Death	2 (4.4%)
Hemorrhagic Stroke**	1 (2.2%)
Need for elective Mitral operation**	1 (2.2%)
Bleeding Complications	1 (2.2%)
Renal Failure	2 (4.4%)
Myocardial Infarction	0 (0.0%)
Respiratory Failure	0 (0.0%)
Cardiac Tamponade	0 (0.0%)

* VARC Guidelines

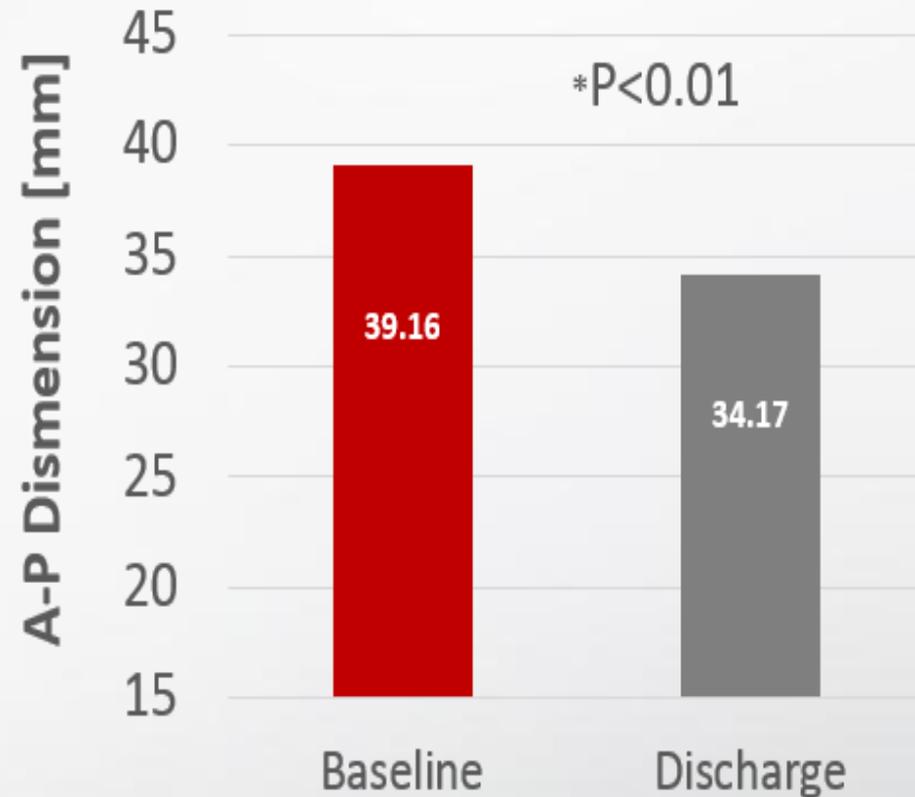
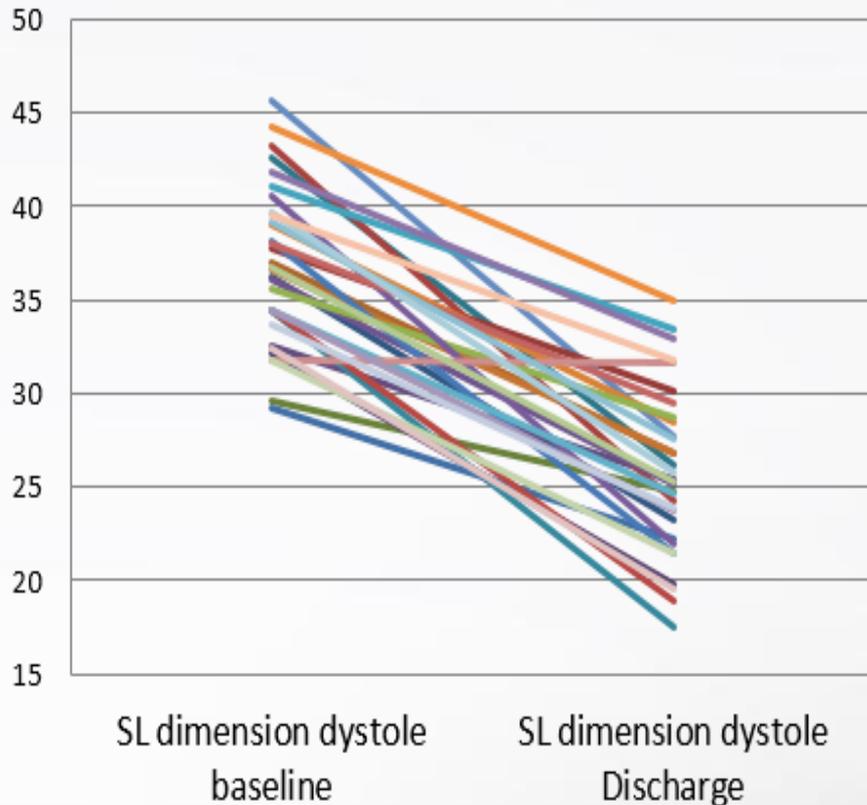
One additional death case per ITT - *compassionate*

Réduction de la régurgitation

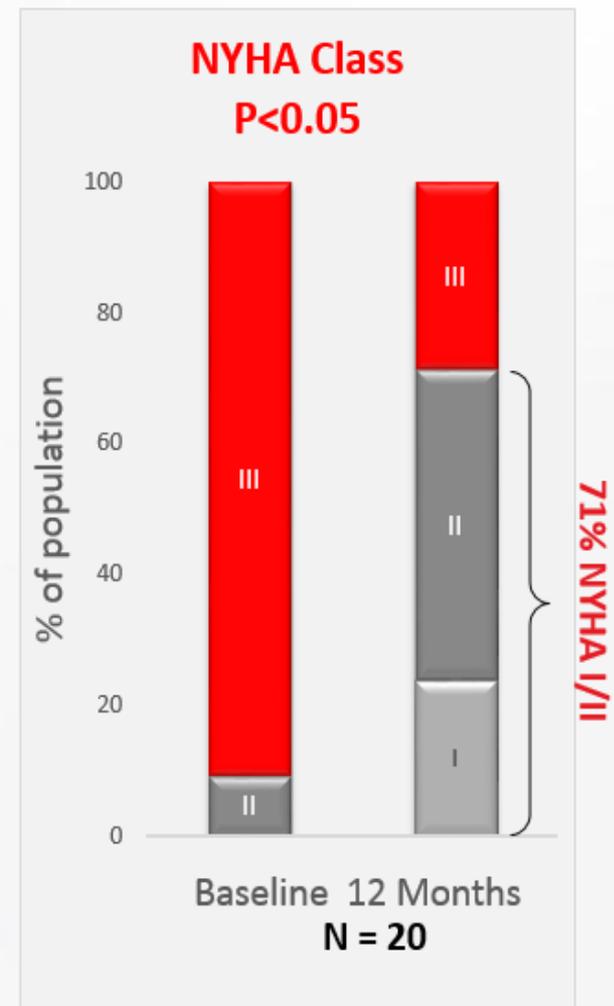
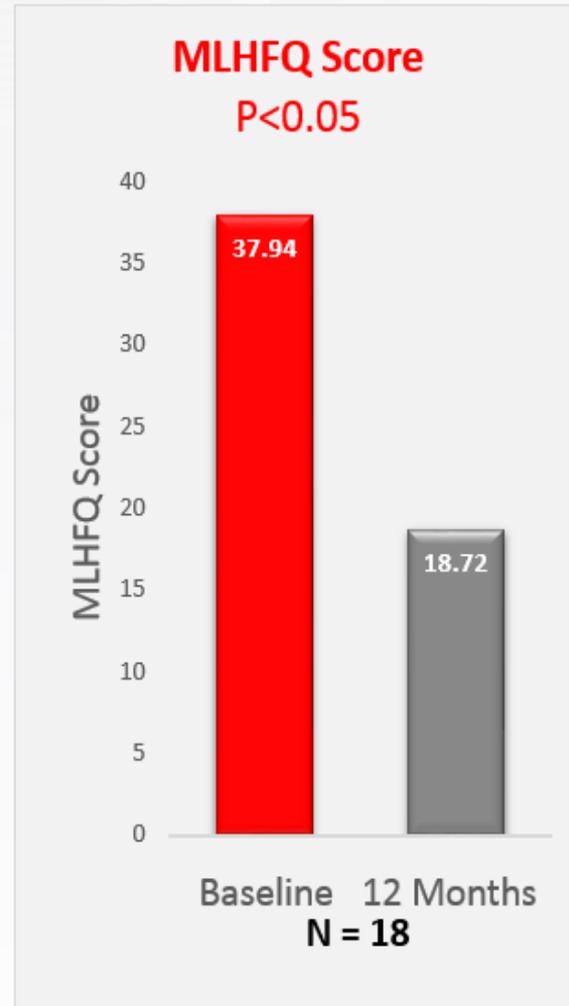
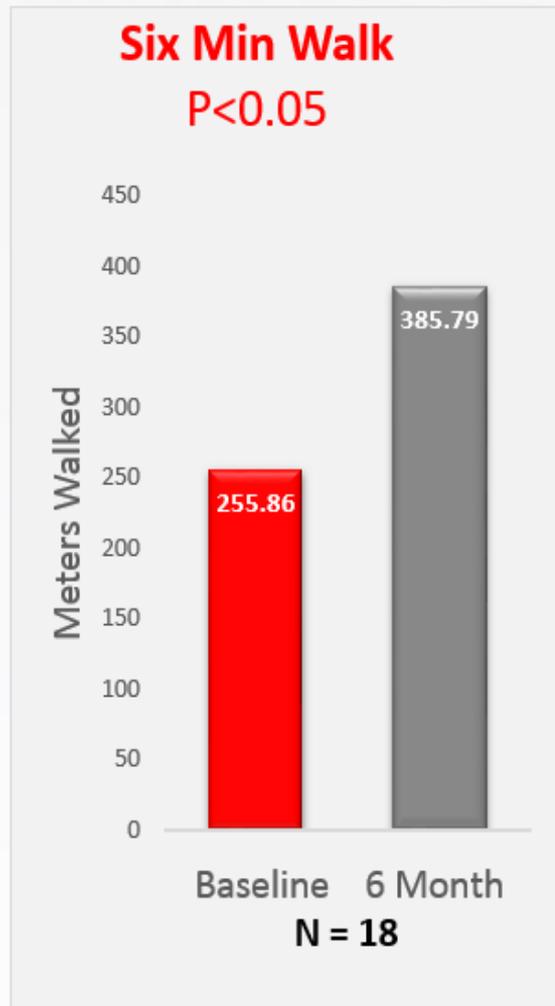


Diminution diamètre anneau mitral

20% average reduction in A-P



Amélioration fonctionnelle à 1 an



Resultats - Synthèse

Effectiveness

- MR \leq 2+ in 6 month follow up (N=21) 87%
- MR \leq 2+ in 12 month follow up (N=18) 95%
- Accumulative implantation time >40 years

Procedure

- Implants successfully deployed on annulus (45/45)
- Intra-procedure MR reduction (43/45)
- Average reduction of septo lateral diameter ~20%

Safety

- Procedural mortality 0/45
- Pre-discharge mortality 2/45*
- **No Device Related Major Adverse Events as adjudicated by independent committee**

*1 at day 7, 1 at day 60

Conclusion

- **Annuloplastie percutanée directe**
 - Transposition percutanée du geste chirurgical (annuloplastie)
 - Méthode prometteuse en cours d'évaluation

- **Le futur: combinaison de techniques ?**

