

# **The PASCAL platform: Successfully and confidently treating MR**

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## Disclosure:

Edwards Lifesciences: Honoraria

# PASCAL Platform for Mitral and Tricuspid Regurgitation

## Central Spacer

Bridge the coaptation gap

## Elongation

Navigate in dense chordae

## Nitinol Design

Passive closure, acute implant flexing

## Independent Clasps

Staged leaflet capture and adjustment

### The PASCAL Platform



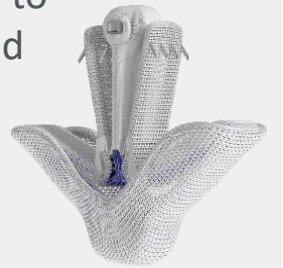
PASCAL Implant



PASCAL Ace Implant

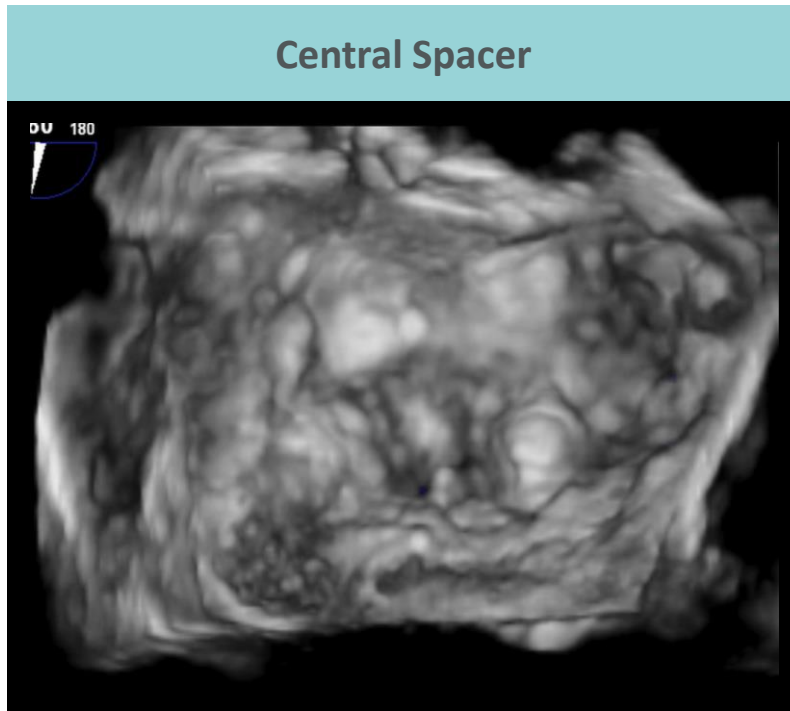
### PASCAL Ace Implant

A narrow profile and central spacer designed to complement PASCAL and provide additional options for patients

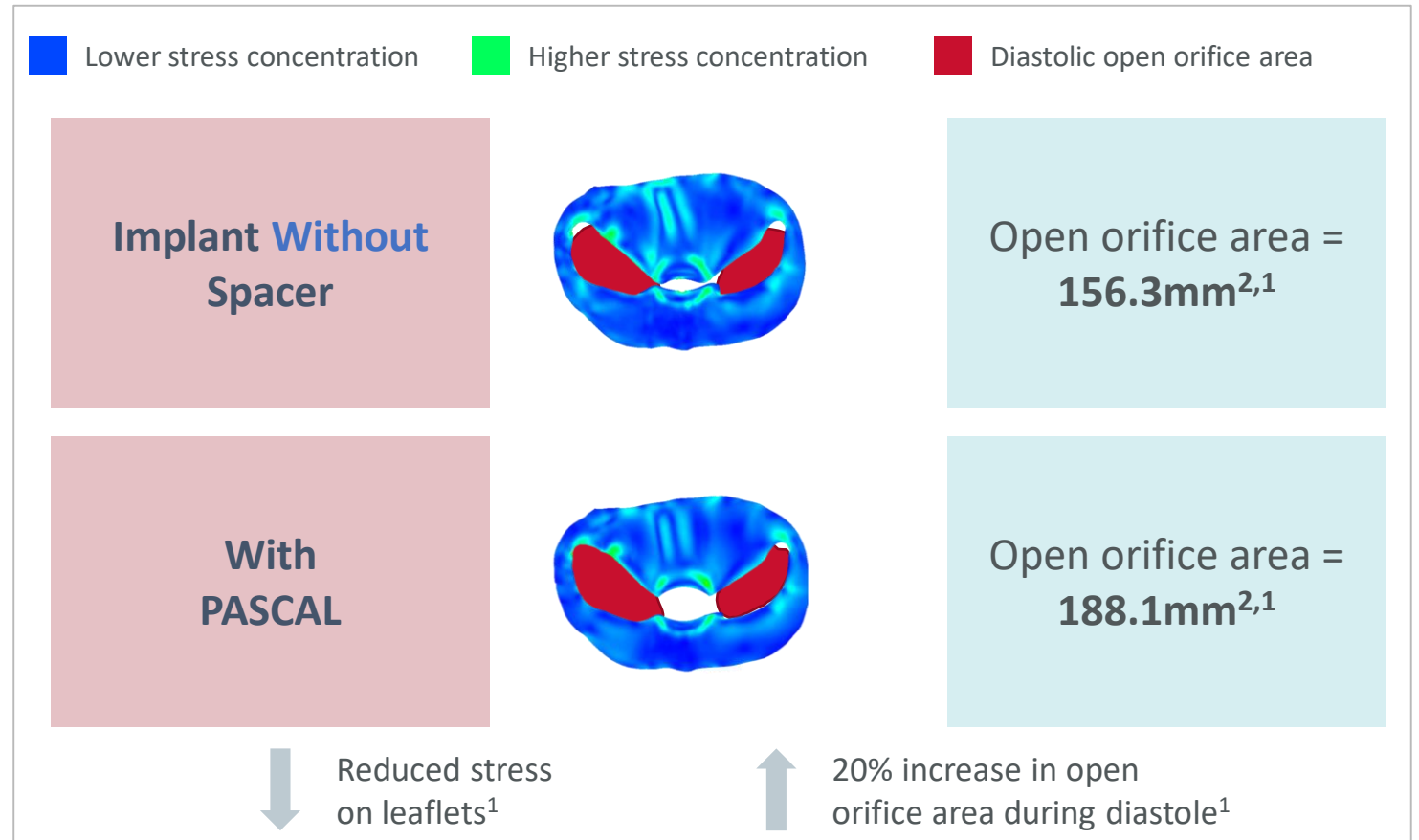


# PASCAL Implant Spacer

Reduces leaflet stress and increases open orifice area for lower transvalvular gradients



Courtesy of Dr. L. Schneider, Ulm, Germany



<sup>1</sup>. Data on file. For professional use. See instructions for use for full prescribing information. CE Marked medical device

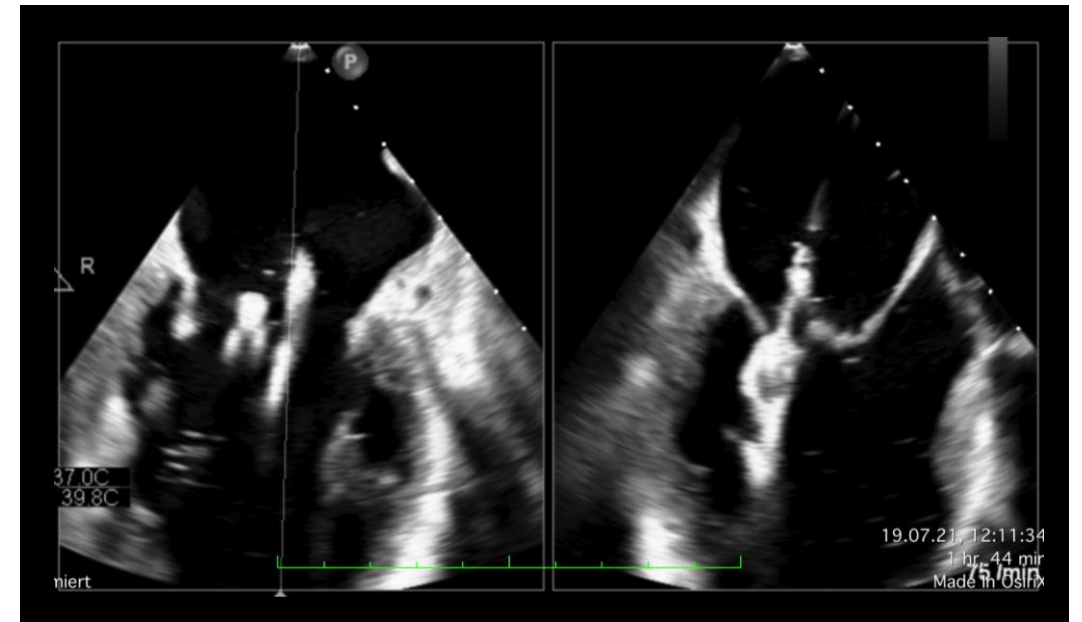
# Optimized Subvalvular Maneuvering

Elongation to ensure procedural confidence

## Elongation & Nitinol Design



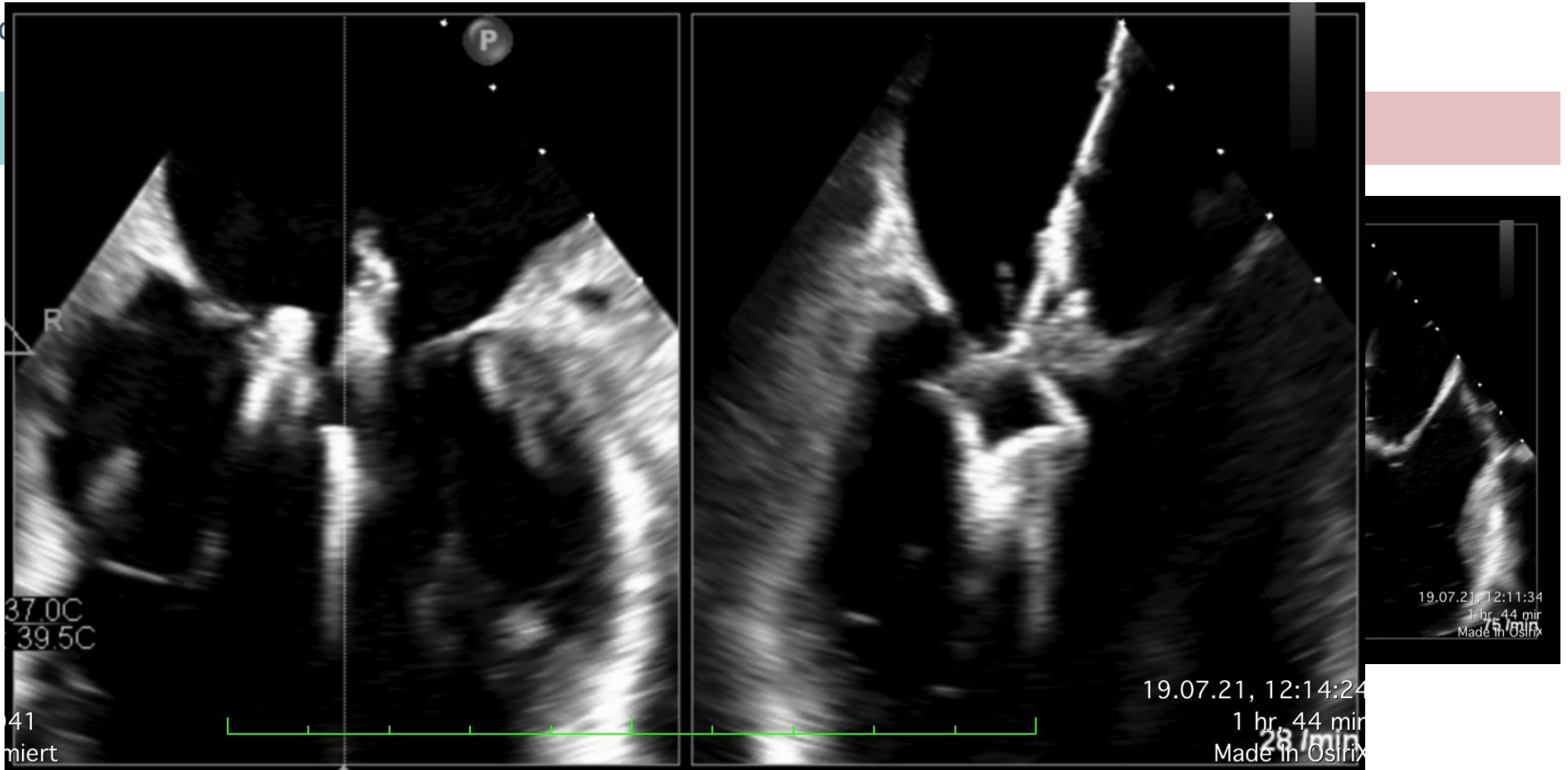
## Elongation & Nitinol Design



Courtesy of Dr. L. Schneider, Ulm, Germany

# Optimized Subvalvular Maneuvering

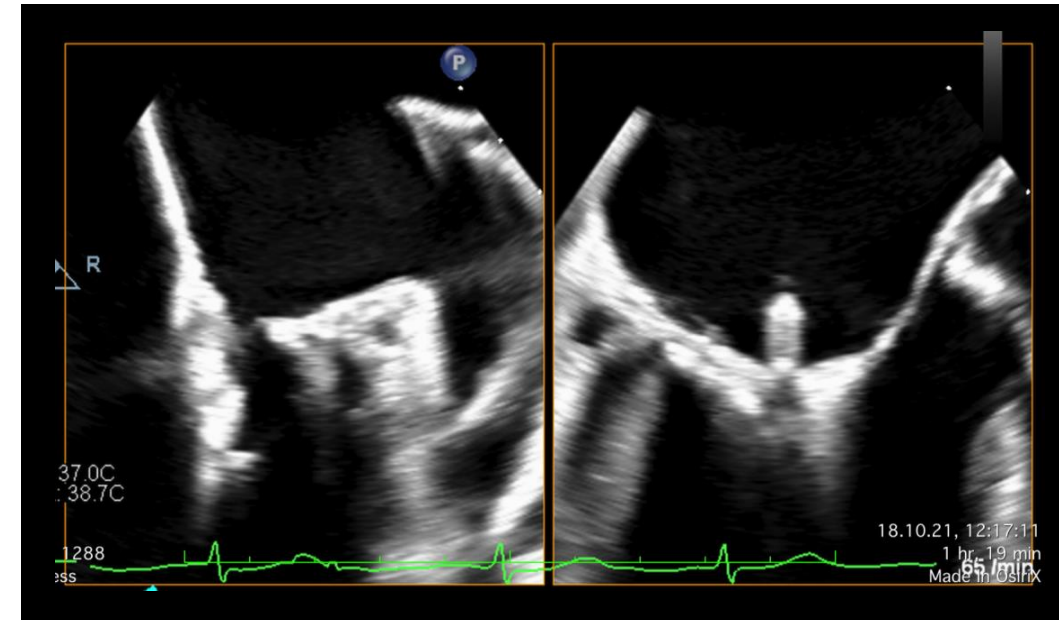
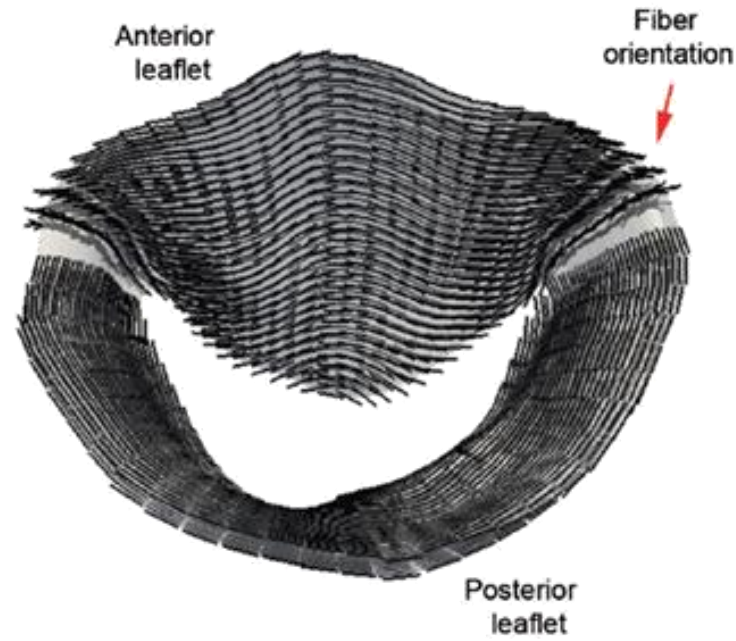
Elongation to



# PASCAL Repair System has Optimized Leaflet Retention Elements

Ensuring firm leaflet capture while minimizing tissue damage

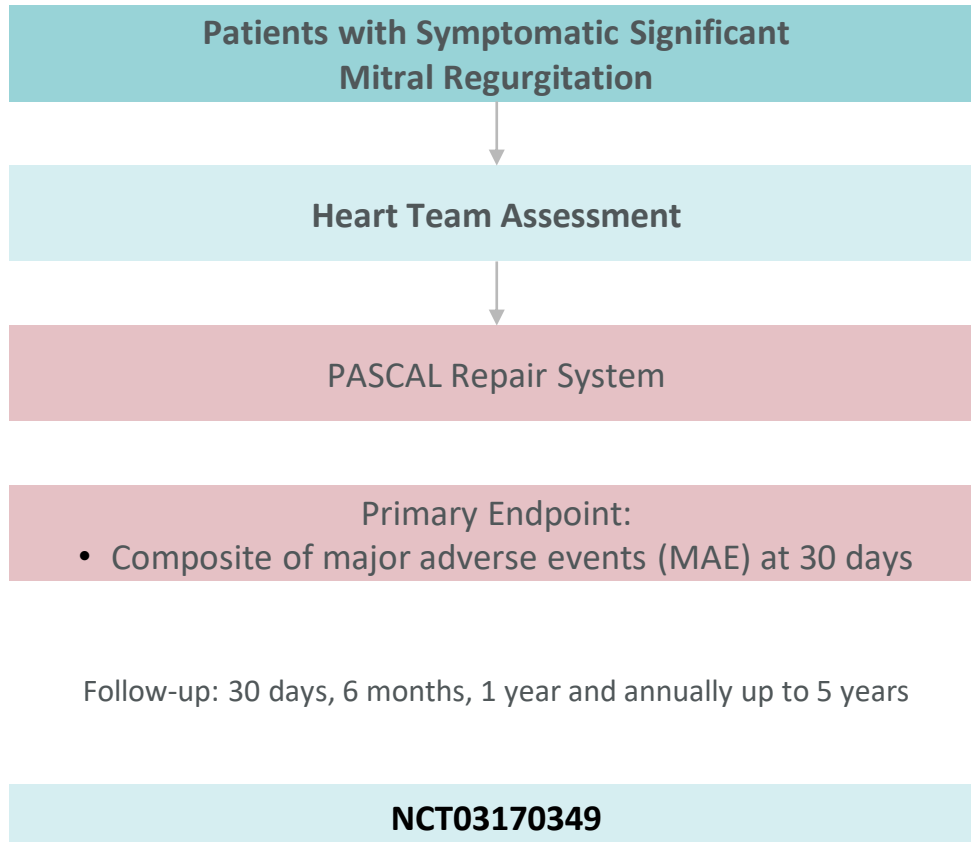
## Independent Clasps



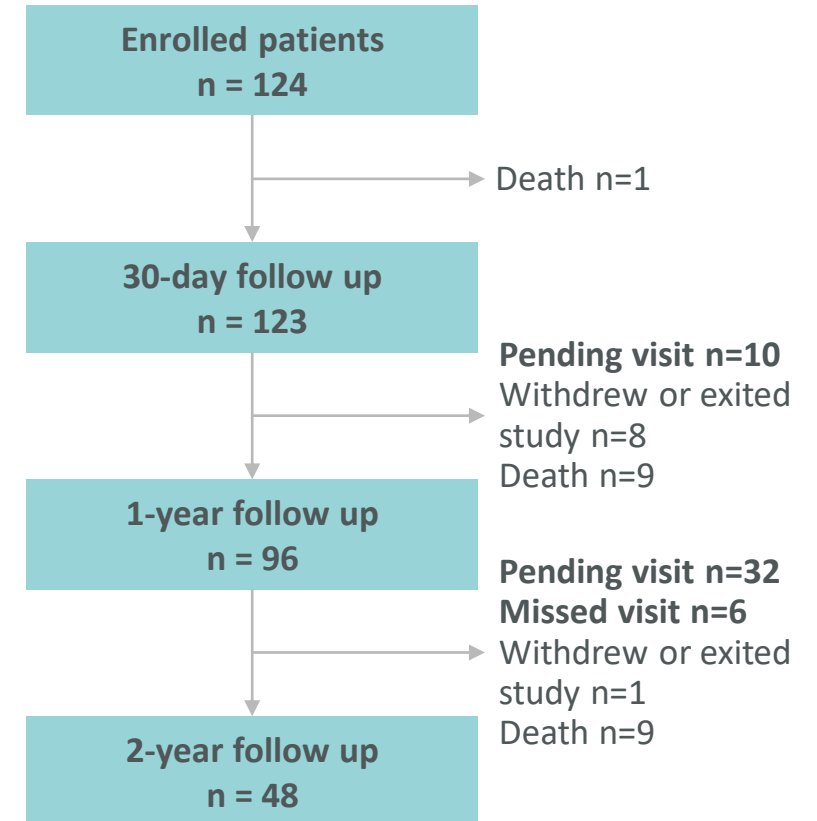
Courtesy of Dr. L. Schneider, Ulm, Germany



# The CLASP Study – PASCAL MR



- MR  $\geq 3+$  as assessed by echocardiography
- NYHA Class II-IVa
- Patient appropriate for the device





# Baseline and Procedural Characteristics

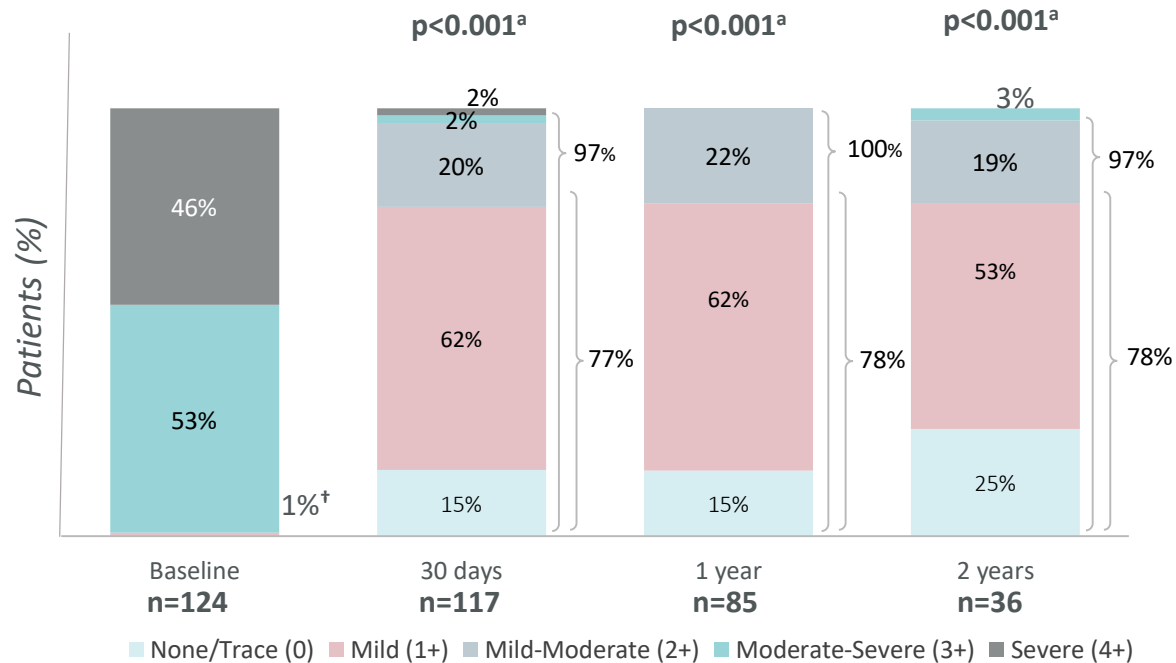
|                                   | <b>N = 124</b><br>% or Mean $\pm$ SD |
|-----------------------------------|--------------------------------------|
| Age, years                        | 75 $\pm$ 11                          |
| Male                              | 56%                                  |
| NYHA functional class III-IVa     | 60%                                  |
| Etiology                          |                                      |
| Functional                        | 69%                                  |
| Degenerative                      | 31%                                  |
| MR severity $\geq$ 3+, TTE or TEE | 100%                                 |
| PISA EROA, cm <sup>2</sup>        | 0.38 $\pm$ 0.15                      |
| Regurgitant volume, ml            | 57 $\pm$ 20                          |
| Vena contracta width, A-P, mm     | 6.3 $\pm$ 1.4                        |

|  | <b>N = 124</b><br>% or Mean $\pm$ SD |
|--|--------------------------------------|
| Successful implant rate*               | 96% (119)                            |
| PASCAL, n=112                          | 96% (107)                            |
| PASCAL Ace, n=12                       | 100% (12)                            |
| Mean # of devices implanted            | 1.4                                  |
| Time of procedure (skin to skin), mins | 124 $\pm$ 59                         |

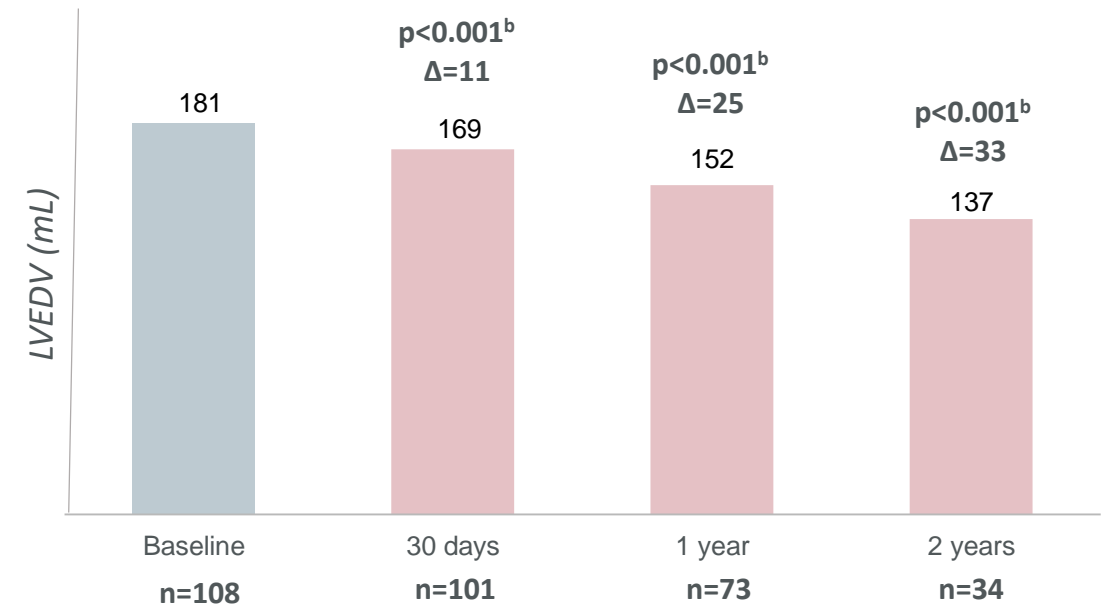
\*Device deployed as intended and delivery system successfully retrieved as intended at time of patient's exit from cardiac catheterization laboratory.  
 Szerlip M, et al. 2-Year Outcomes for Transcatheter Repair in Patients with Mitral Regurgitation from the CLASP Study. J Am Coll Cardiol Intv 2021;14:1538–48

# Sustained MR Reduction & Positive LV Remodeling at 2 Years

## CLASP Study Sustained MR reduction at 2 years by core lab<sup>1</sup>



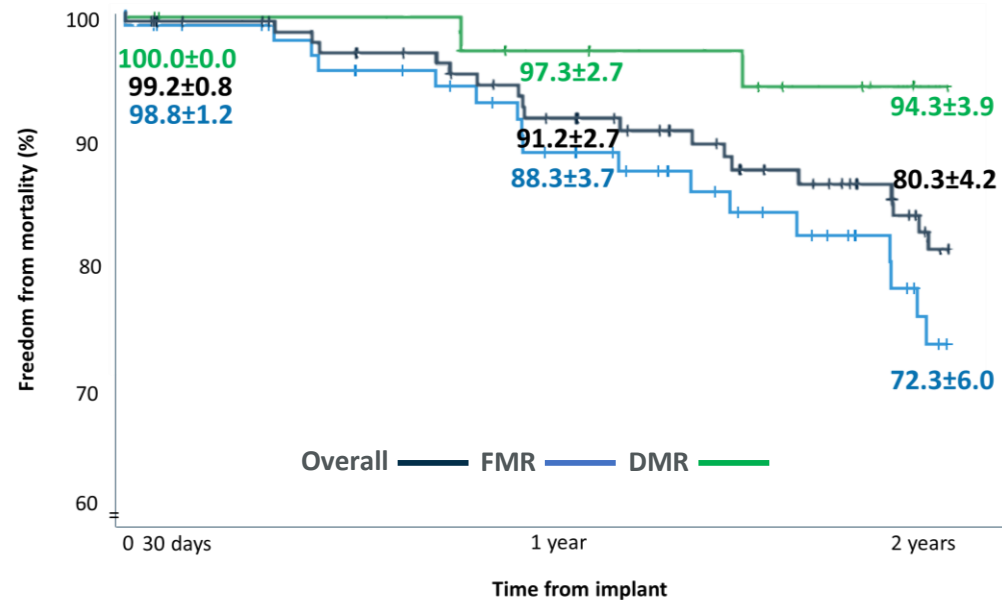
## Positive LV Remodeling



<sup>1</sup>Cardiovascular Core Lab at Morristown Medical Center, Morristown, NJ, USA. p-value calculated from paired analysis using Wilcoxon signed rank test. .<sup>†</sup>One patient had MR 1+ by TTE although 3+ by TEE. LVEDV Δ and p-value presented for paired analysis; p-value calculated using Student's T-test, <sup>a</sup>baseline vs. 30 days (n=117), 1 year (n=85), and 2 years (n=36), <sup>b</sup>baseline vs. 30 days (n=91), 1 year (n=67), and 2 years (n=30) LVEDV: left ventricular end diastolic volume M. Szerlip M.et. al. 2-Year Outcomes for Transcatheter Repair in Patients With Mitral Regurgitation From the CLASP Study. J Am Coll Cardiol Interv 2021;14:1538–48.

# Survival and Heart Failure Hospitalization

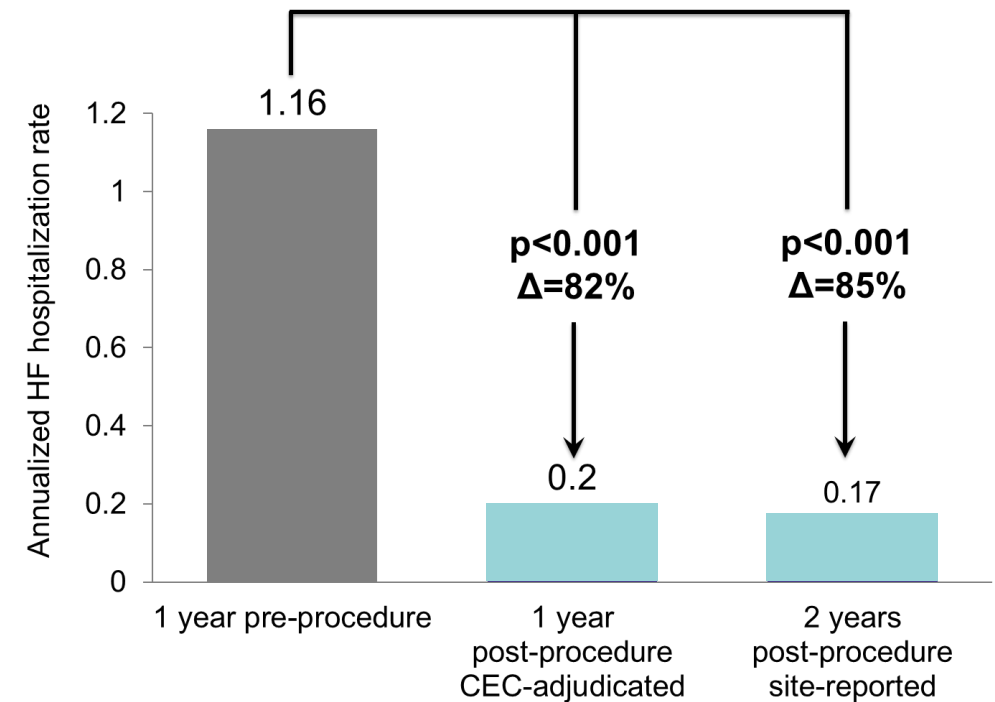
## 80% Survival at 2 Years<sup>1</sup>



Patients at risk

|         |     |     |    |    |
|---------|-----|-----|----|----|
| Overall | 124 | 119 | 98 | 55 |
| DMR     | 39  | 37  | 34 | 26 |
| FMR     | 85  | 82  | 64 | 29 |

## 85% Reduction in Annualized HF Hospitalization Rate at 2 Years



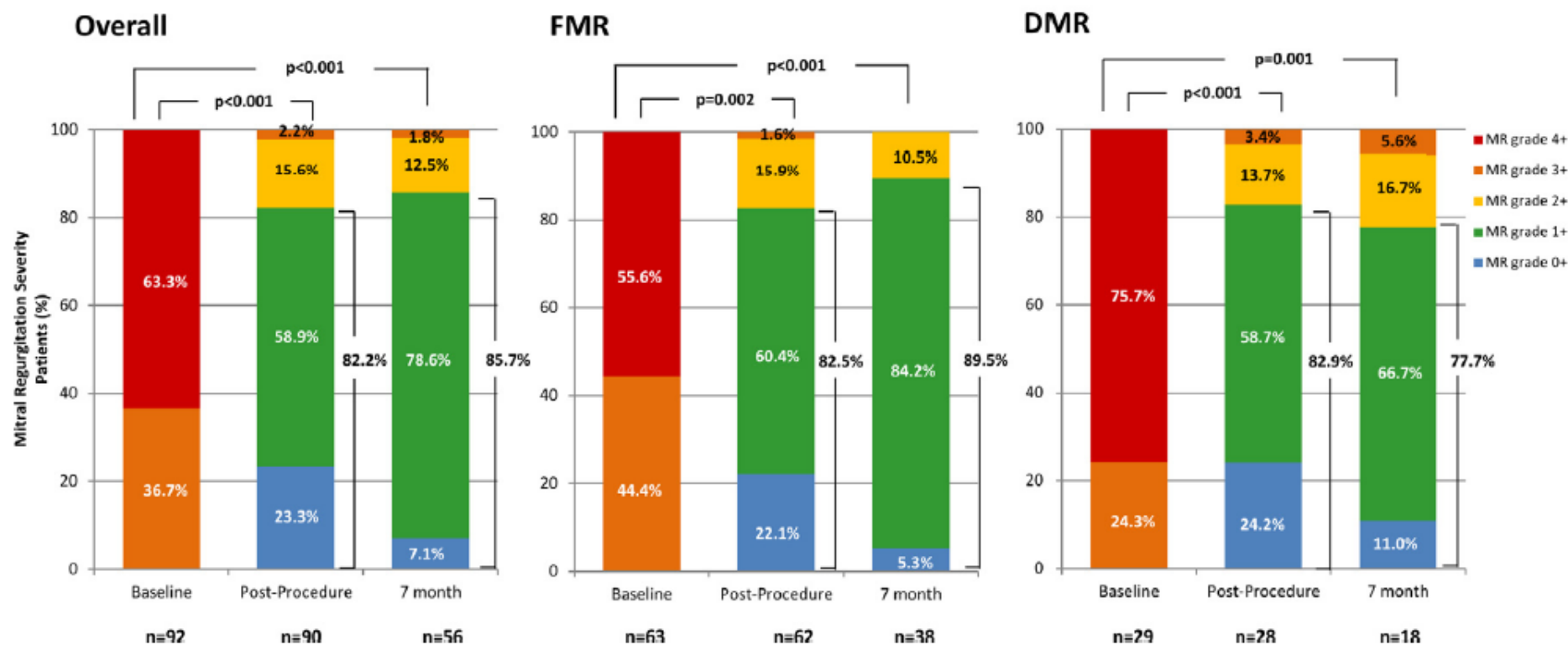
<sup>1</sup>Kaplan-Meier analysis time to first event  $\pm$  SE.

Szerlip M, et al. 2-Year Outcomes for Transcatheter Repair in Patients with Mitral Regurgitation from the CLASP Study. J Am Coll Cardiol Interv 2021;14:1538–48

# PASCAL Repair System – center experience from Bad Neustadt<sup>1</sup>

→ Significant and durable MR reduction in all aetiologies

MR reduction



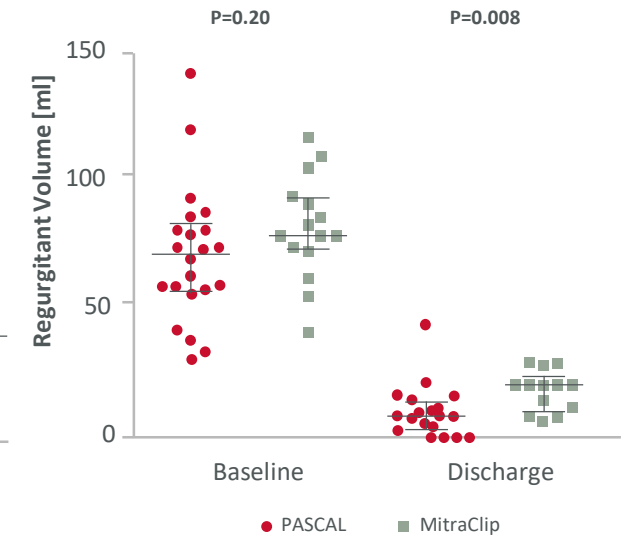
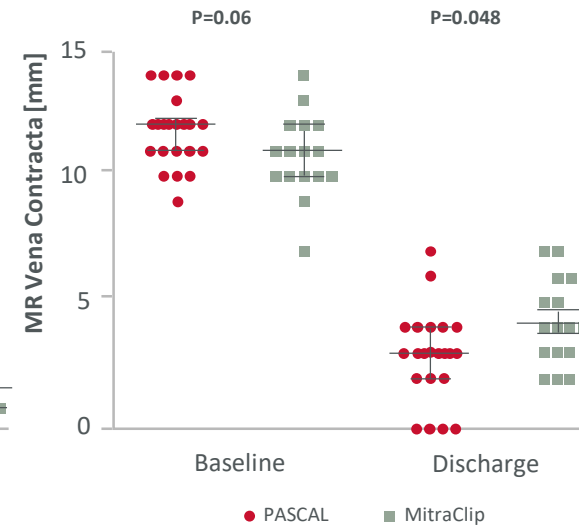
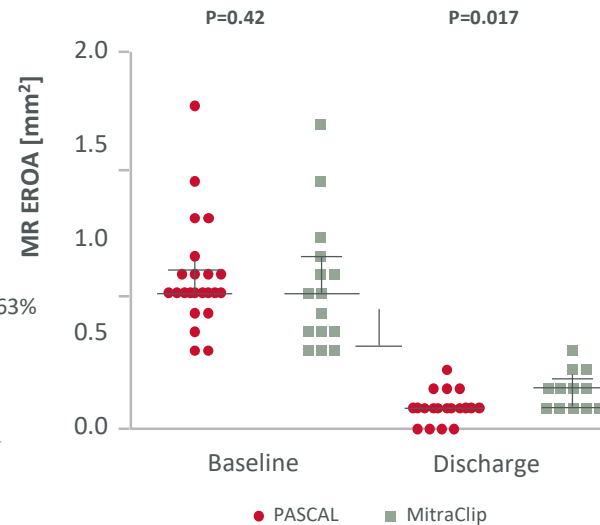
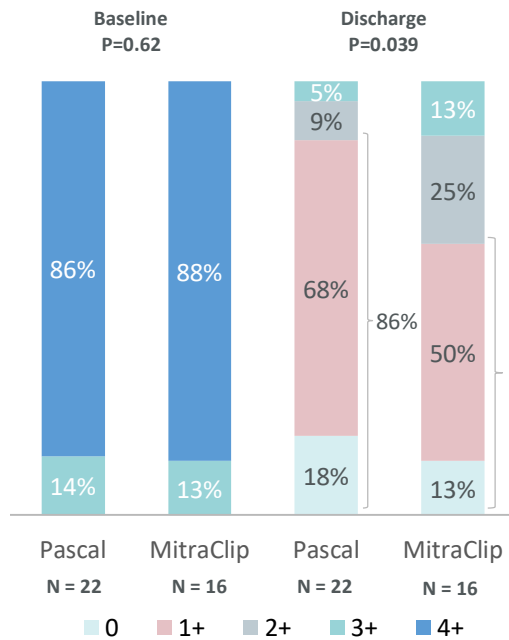
# PASCAL Repair System vs MitraClip for DMR, Bad Oeynhausen<sup>1</sup>

Larger MR reduction with the PASCAL repair system (paired analysis)

EROA reduction

VC reduction

Regurgitant Volume reduction

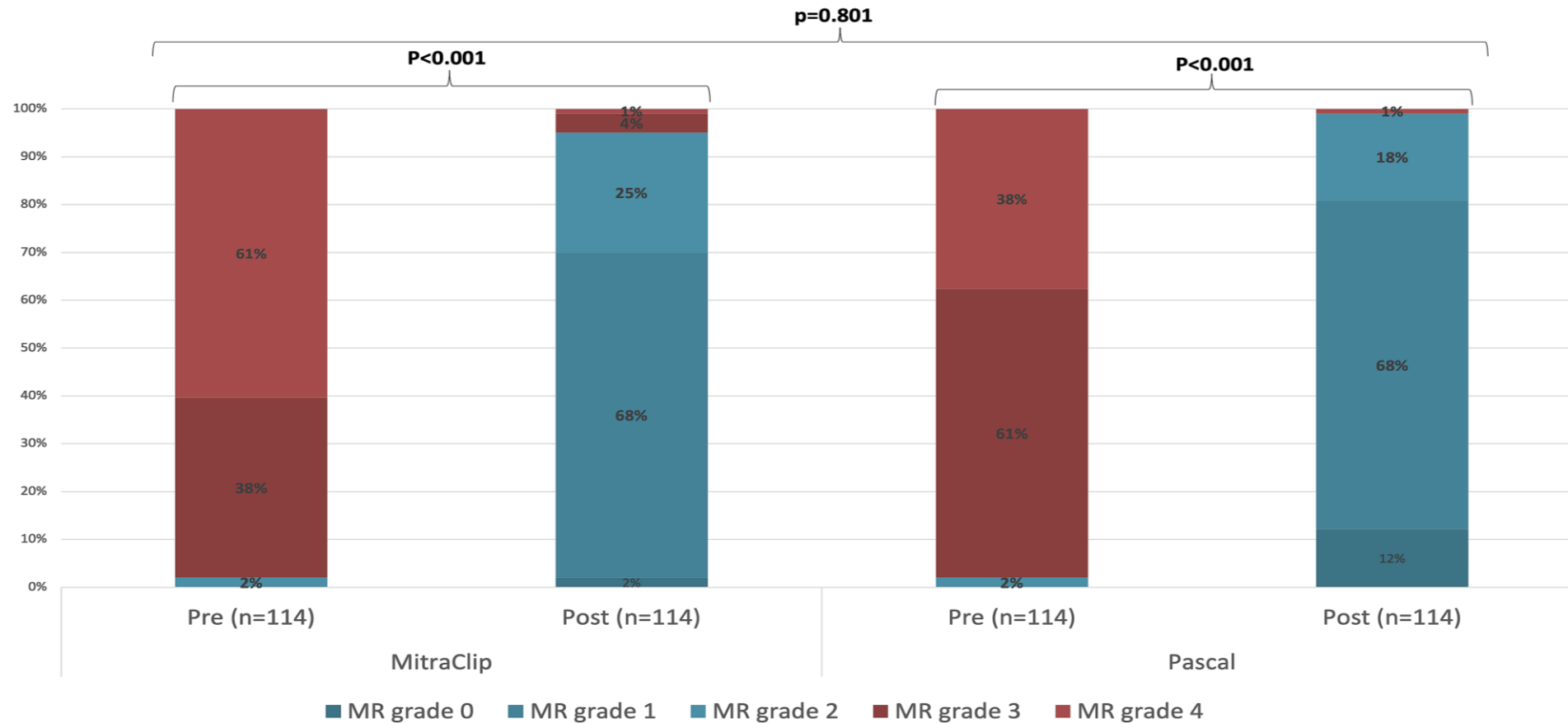


Adapted from Gerçek M. et al. Clin Res Cardiol. 2021 Apr 10.

**MR grade ≤1+: 86.4% PASCAL vs. 62.5% MitraClip (p=0.039)<sup>1</sup>**

<sup>1</sup>Gerçek M et al. Clin Res Cardiol. 2021 Apr 10. doi: 10.1007/s00392-021-01845-8. <sup>2</sup>Paired analysis. Procedural success 95.5% for PASCAL Implant; Procedural success 87.5% for MitraClip. EROA, effective regurgitant orifice area; MR, mitral regurgitation; VC, vena contracta.

# PASCAL Repair System vs MitraClip multicenter evaluation, (Ulm<sup>1</sup>, Bad Oeynhausen<sup>2</sup>, Munich<sup>3</sup>)

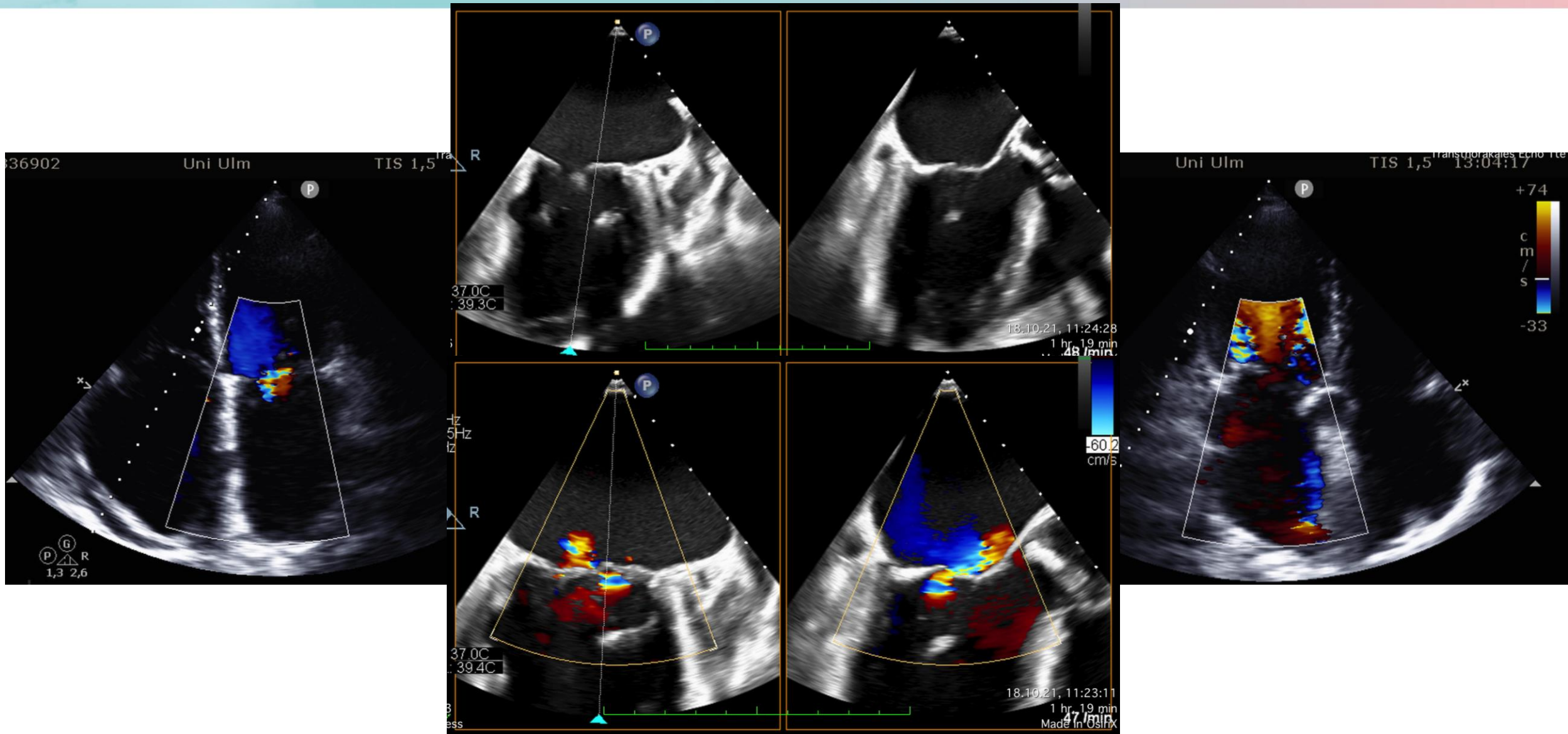


MR reduction:  $2.29 \pm 0.82$  MitraClip vs.  $2.46 \pm 0.82$  PASCAL ( $p=0.191$ )

## Case Presentation

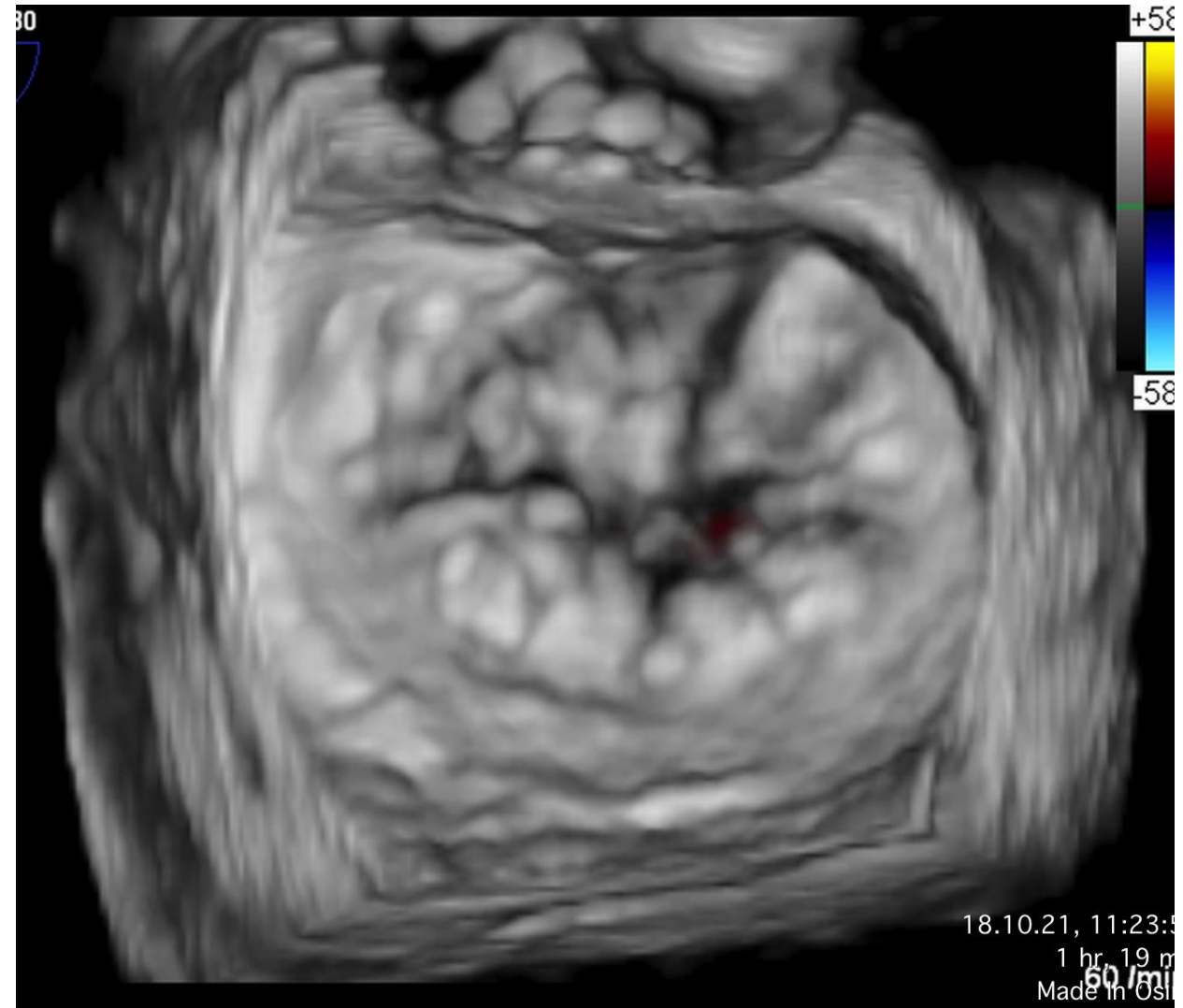
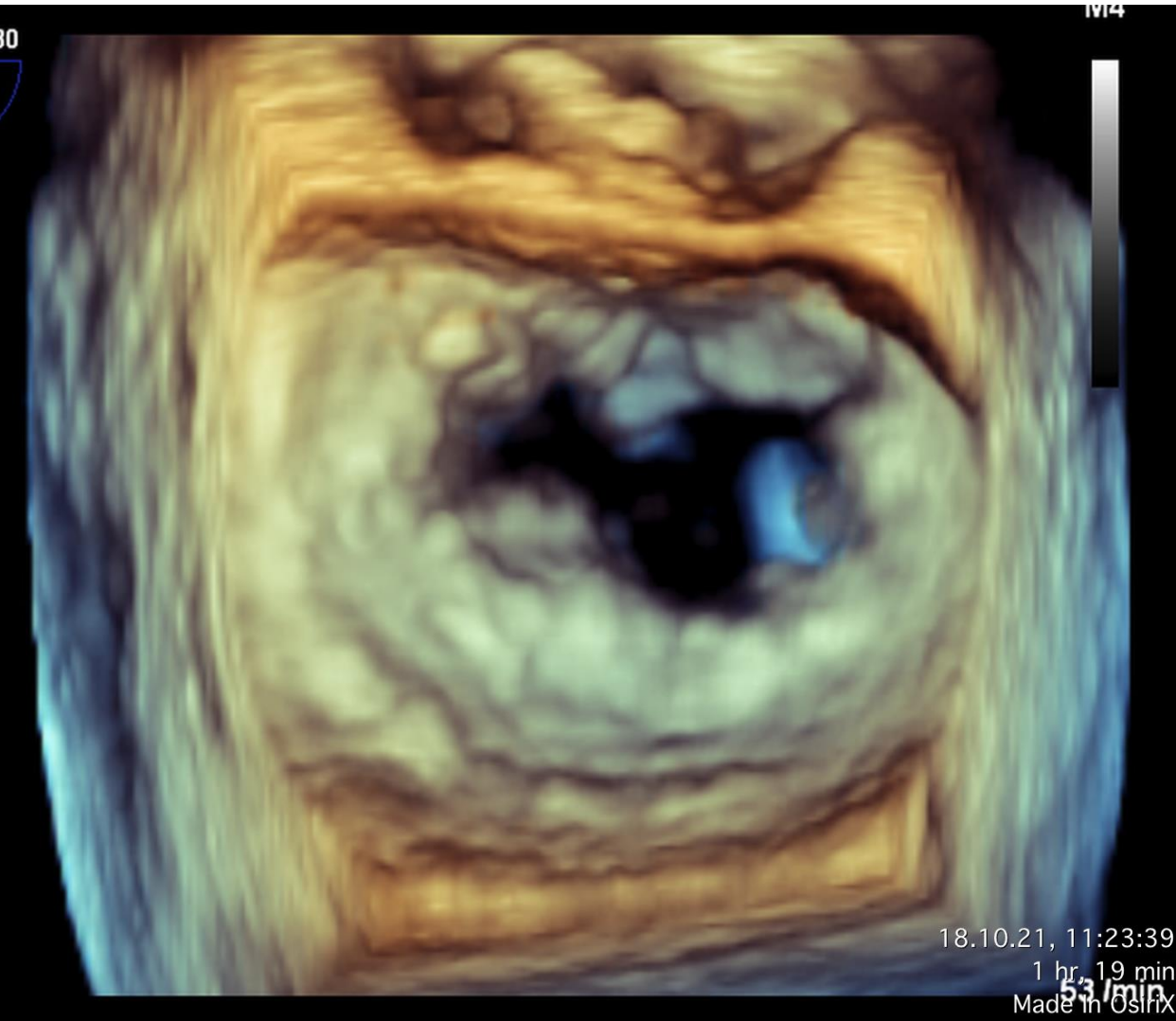
- 82y male
- Dyspnea NYHA III
- Several episodes of decompensated heart failure
- CAD without relevant stenosis
- Permanent Afib
- Postcapillary pulmonary hypertension
- Moderate-severe eccentric DMR due to prolapse and mini-flail in P1
- Severe MAC and calcified papillary muscles, chordae and leaflets





# EuroValve

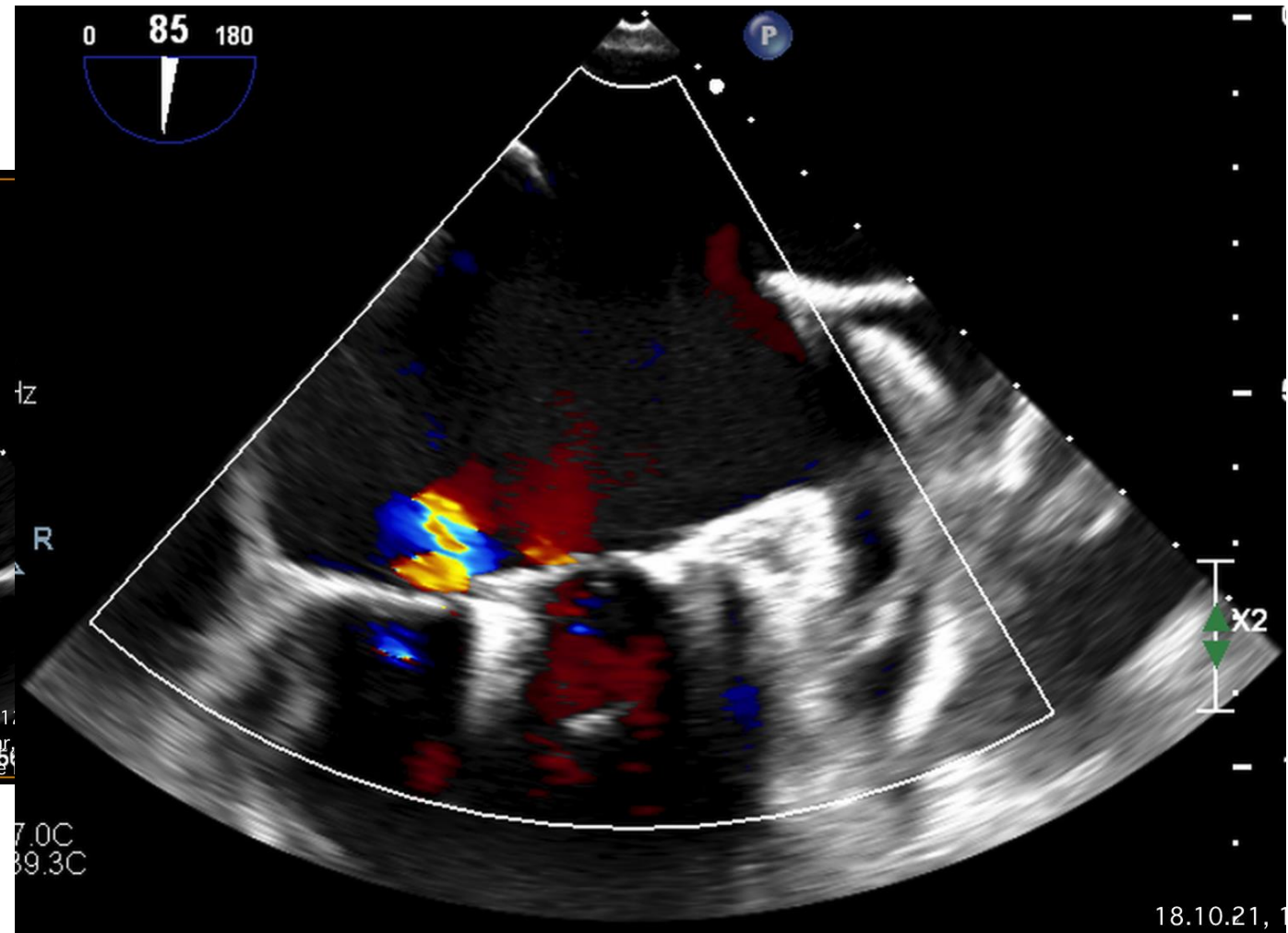
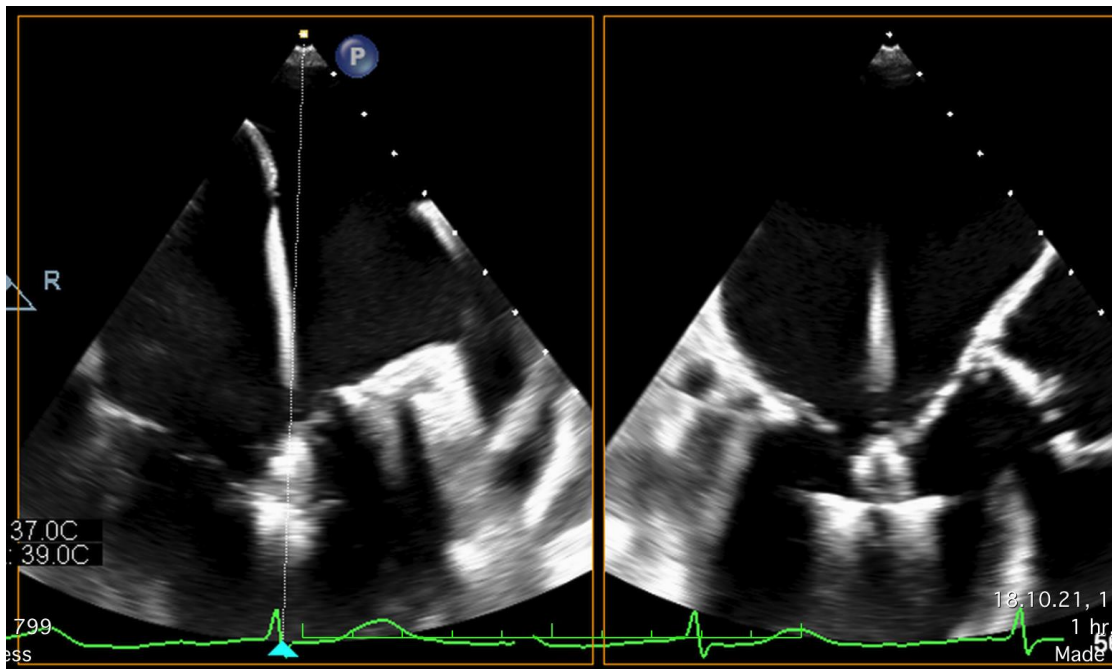
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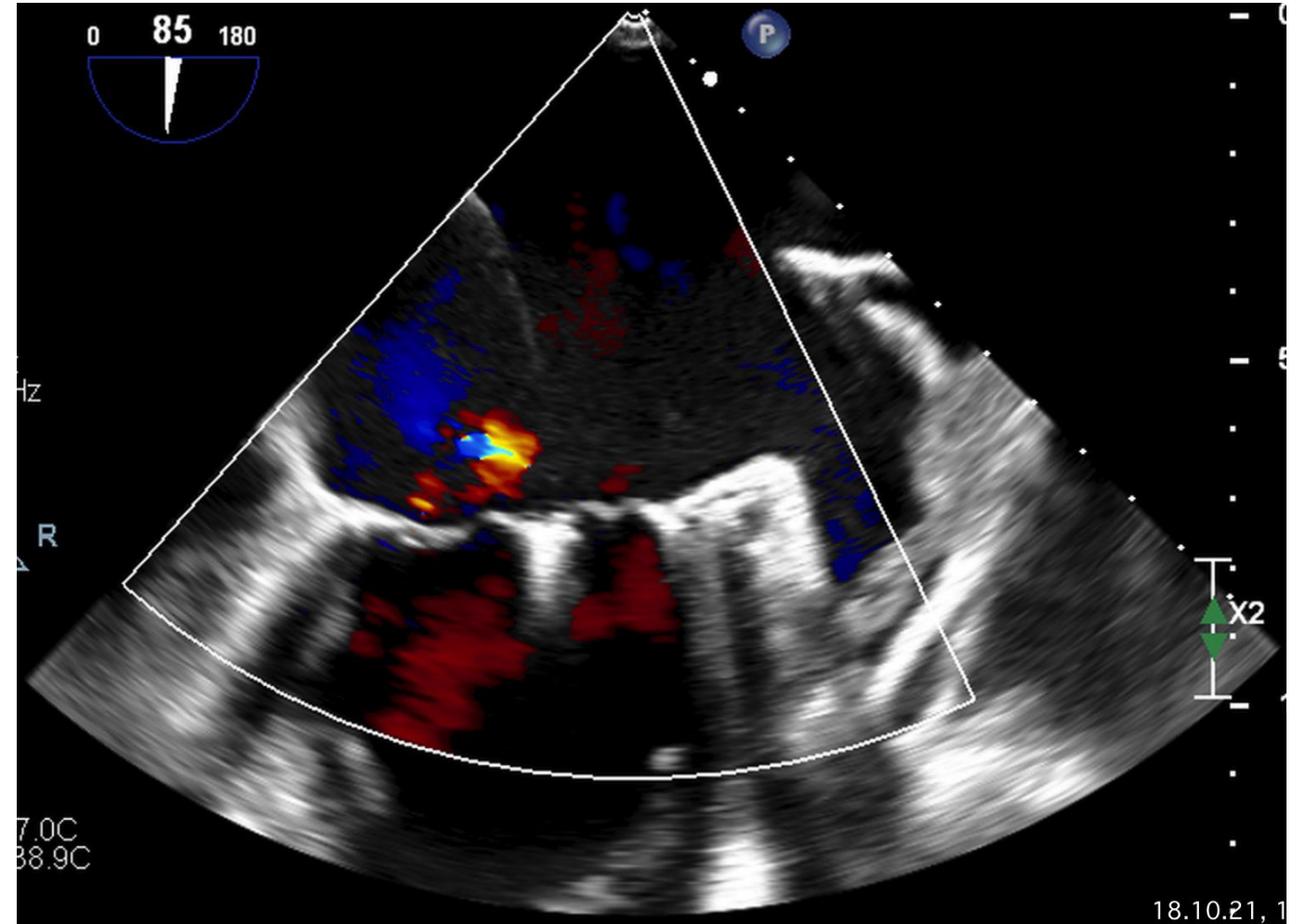
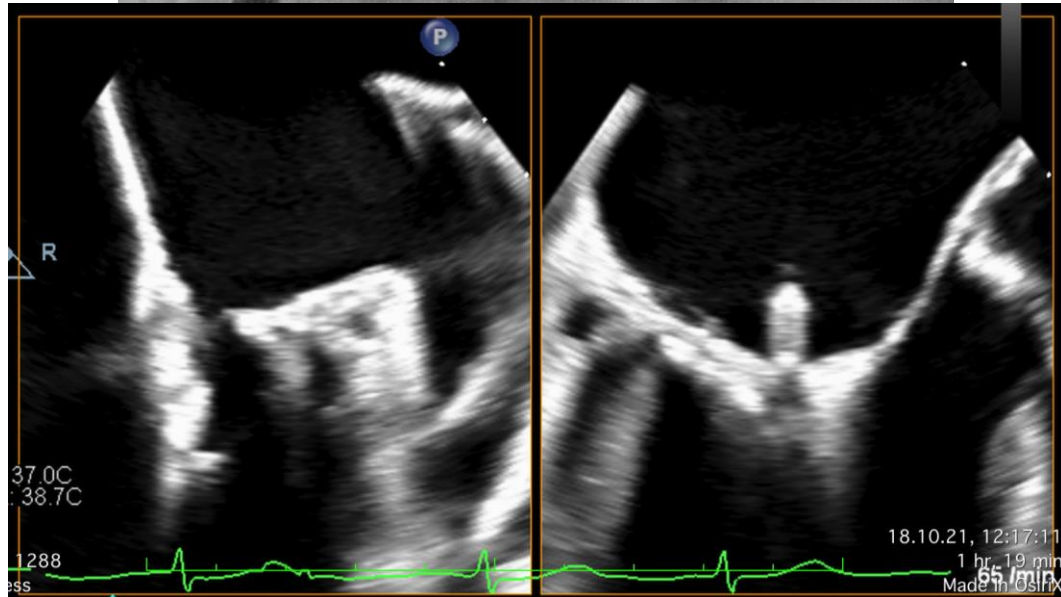
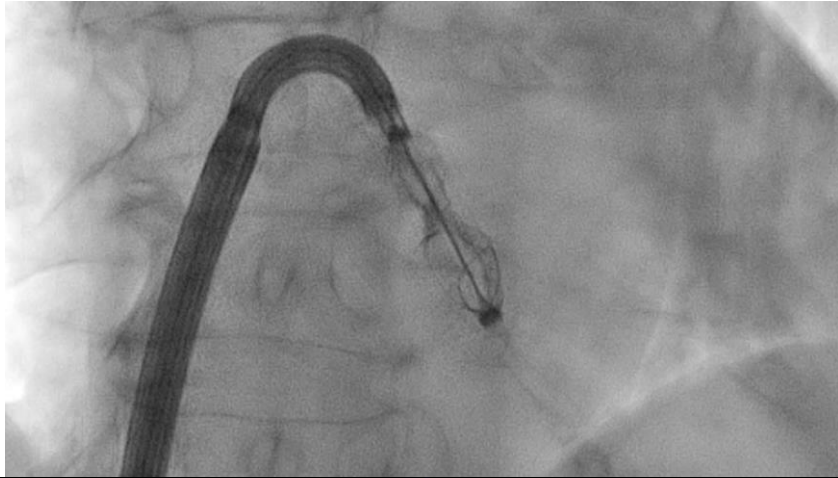
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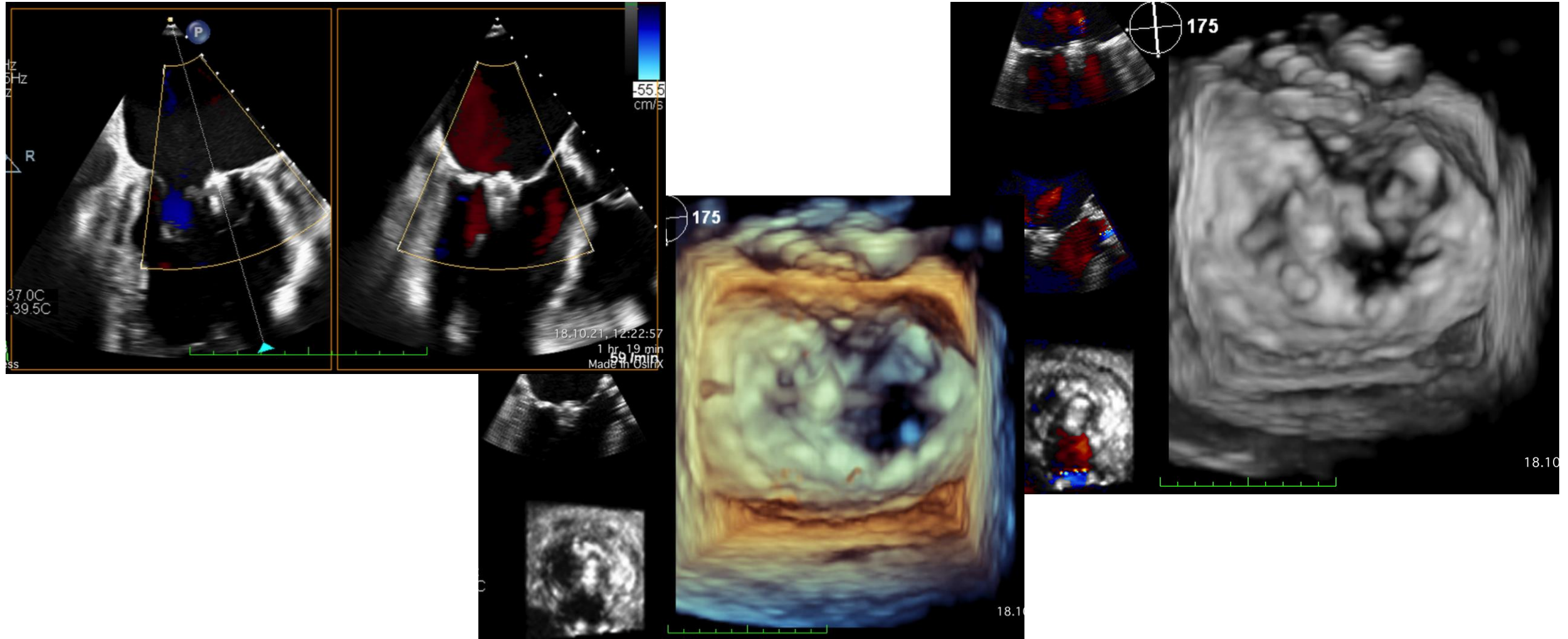
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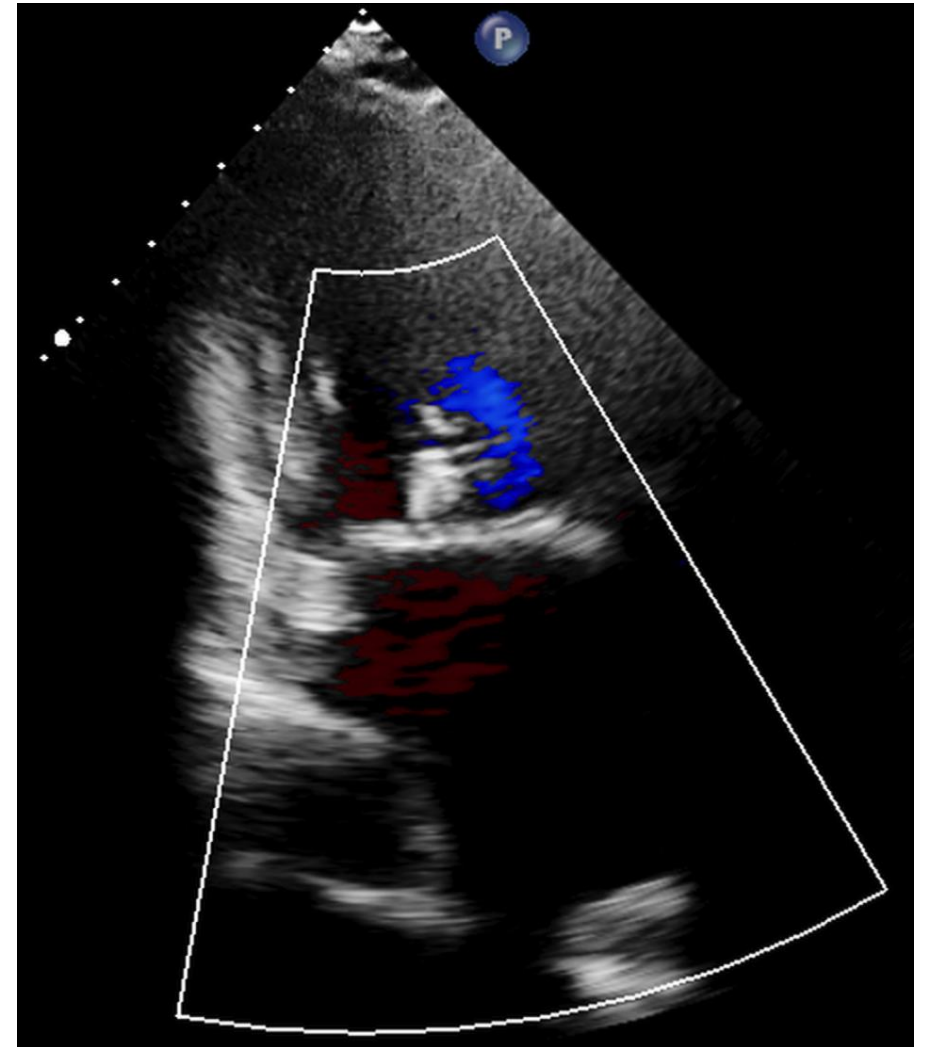
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# Conclusions

- The PASCAL Platform is a novel and differentiated therapy for patients
- **In the CLASP study at 2 years follow up:**
  - High survival rates and low heart failure hospitalization rates
  - Robust and durable MR reduction
  - Positive LV remodeling
- **Single center experiences:**
  - Significant and sustained improvements in MR reduction, NYHA, Exercise Capacity and Quality of Life
  - PASCAL repair system showed larger MR reduction rates compared to MitraClip in a DMR patient cohort in a study from Bad Oeynhausen
- **Multicenter center experience:**
  - Excellent and comparable procedural success and 30-day outcome with a tendency towards larger MR reductions using the PASCAL repair system compared to MitraClip



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Thank you!