TURIN,
October
25th-27th
2018
Starhotels
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GIORNATE
CARDIOLOGICHE
TORINESI

UNIVERSITÁ DEGLI STUDI DI TORINO

AZIENDA OSPEDALIERO - UNIVERSITARIA
Città della Salute e della Scienza di Torino

"I go for transventricular mitral valve repair with 1st generation e-PtFE chordae"

Giovanni Speziali, M.D.
Pittsburgh, PA - USA

Financial Disclosure

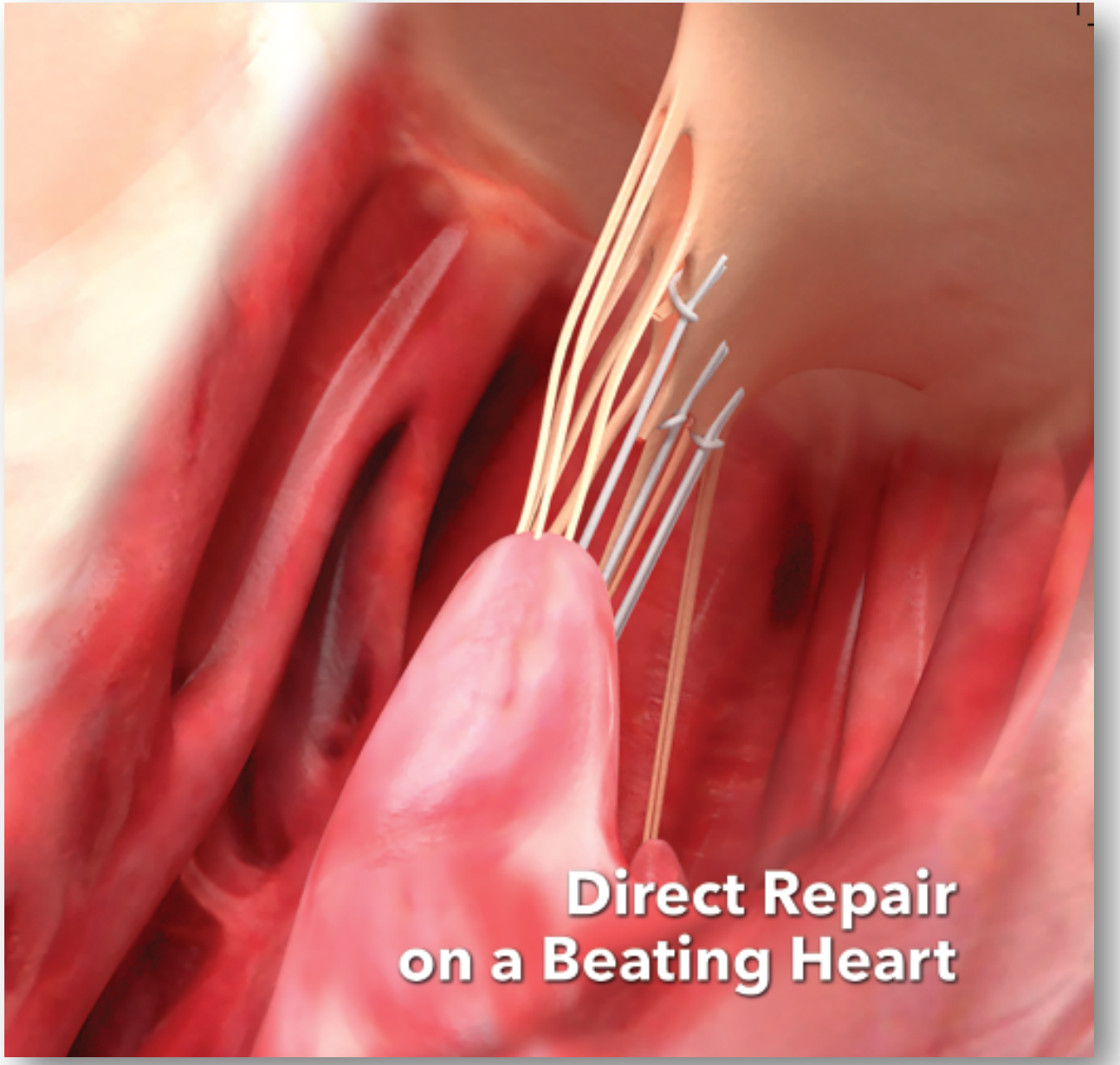
I am co-founder and stockholder of NeoChord, Inc.

The Neochord Operation

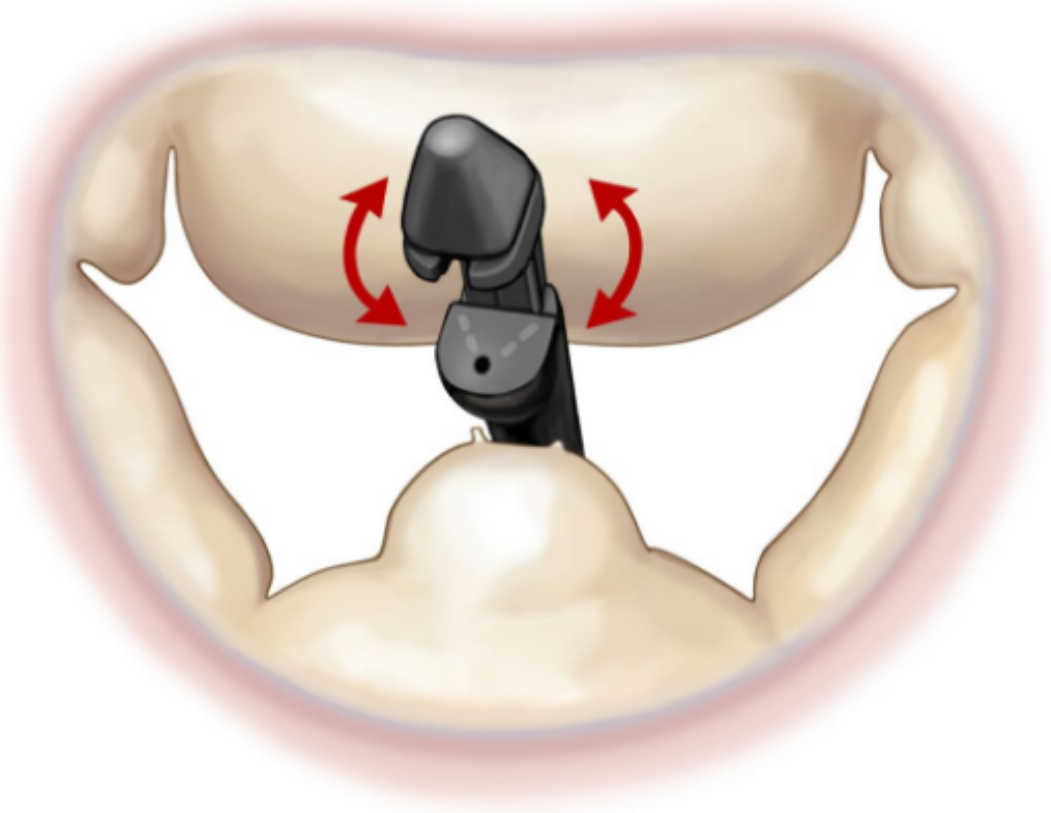
Beating heart procedure for the treatment of DEGENERATIVE MITRAL VALVE REGURGITATION

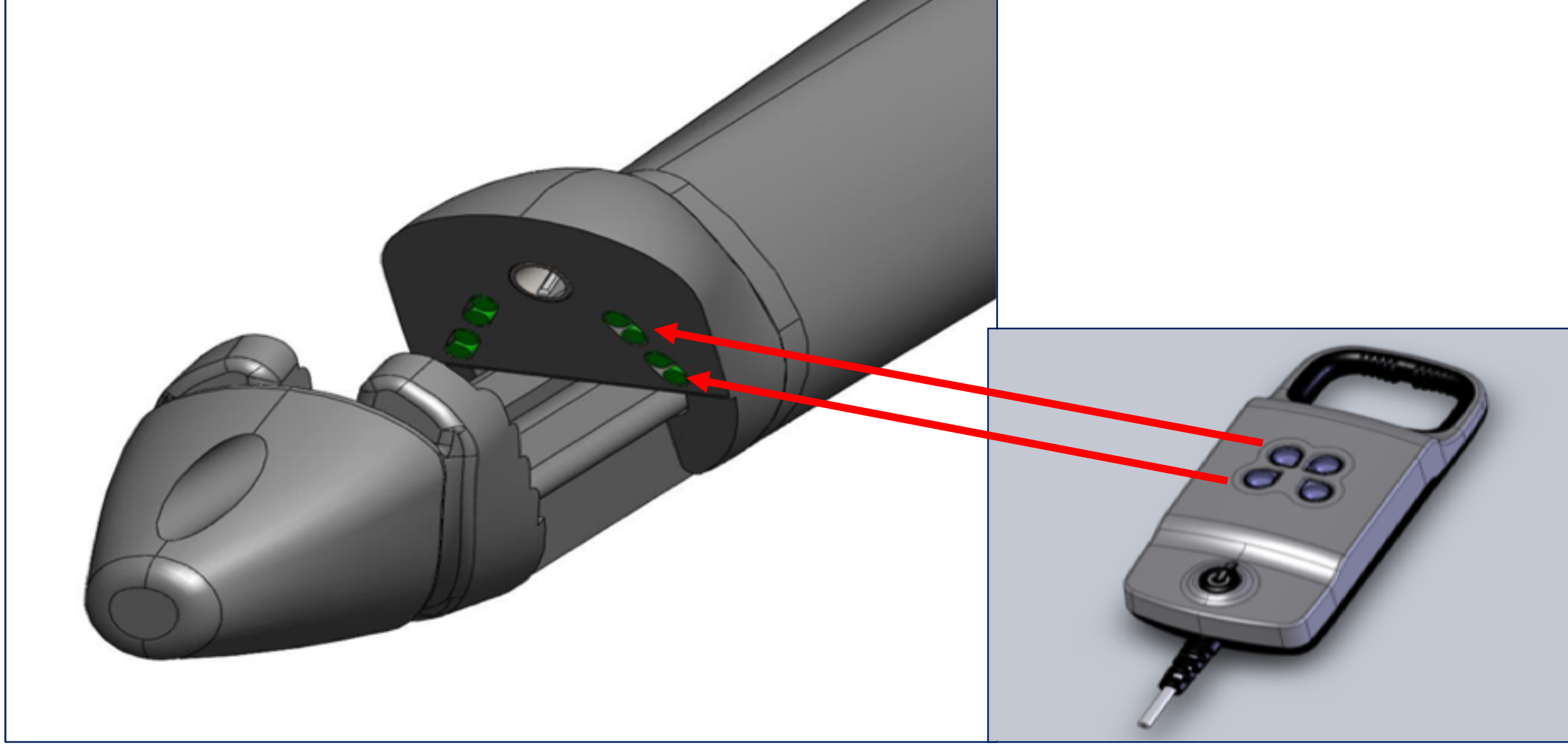
Off pump avoids complications due to bypass and aortic cross-clamp

Real-time visual guidance by TEE
1. No ionizing radiation to patient or cardiac team
2. Allows dynamic adjustment of chord lenght versus static adjustment in standard surgery



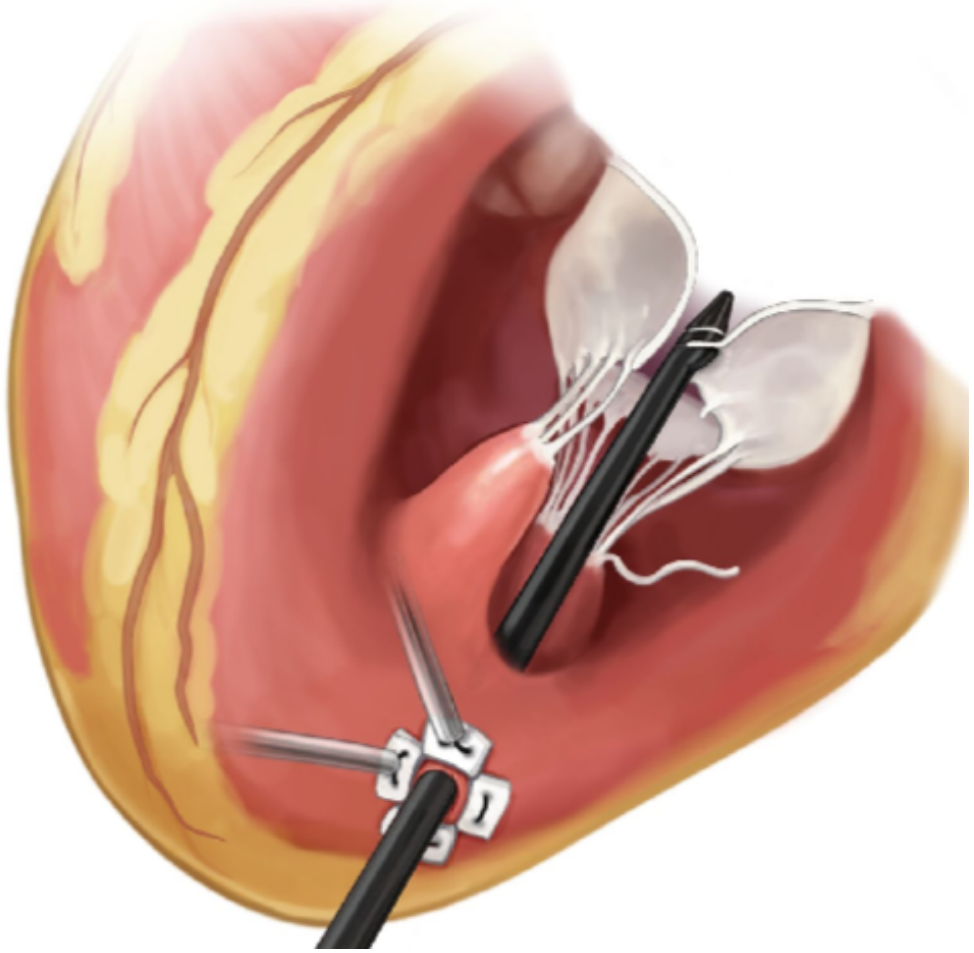

Reloadable Suture Cartridges
Multi-Use Needles
Delivery Instrument
Leaflet Capture Verification Monitor
NeoChord DS1000 System





Confirmation of grasp (Fiberoptics)

Leaflet Capture and Verification System
Fiber Optic Confirmation



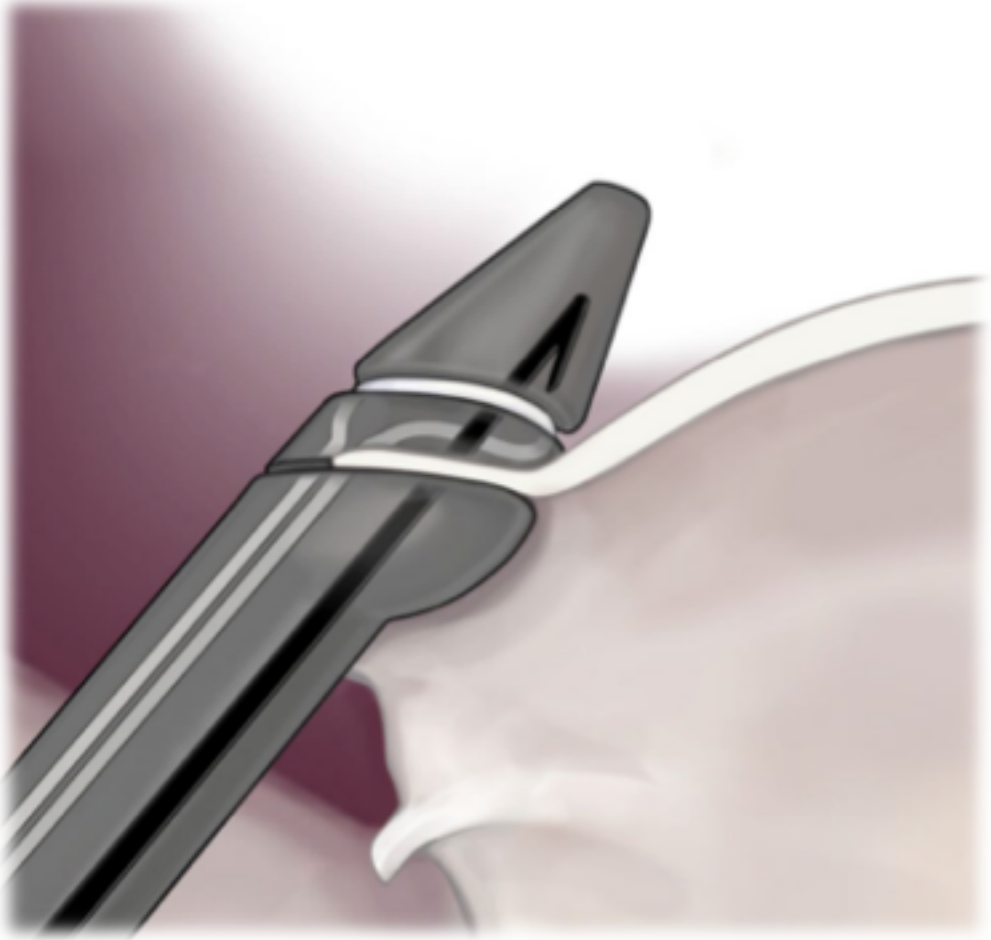
No Capture

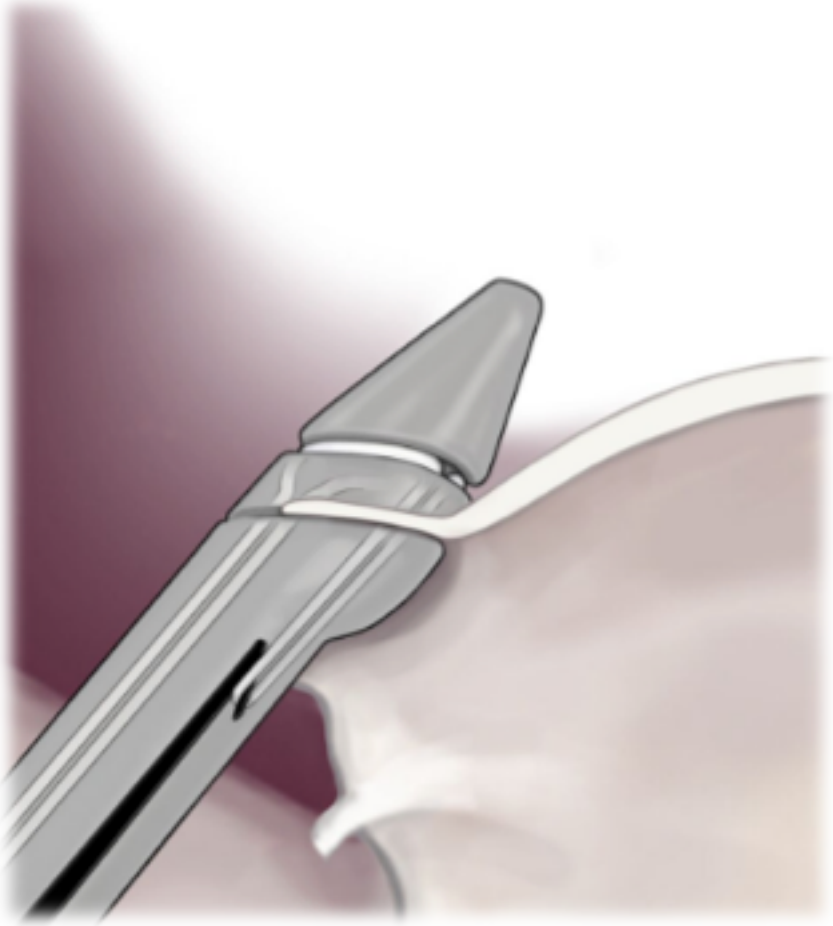
Partial Capture

Complete Capture

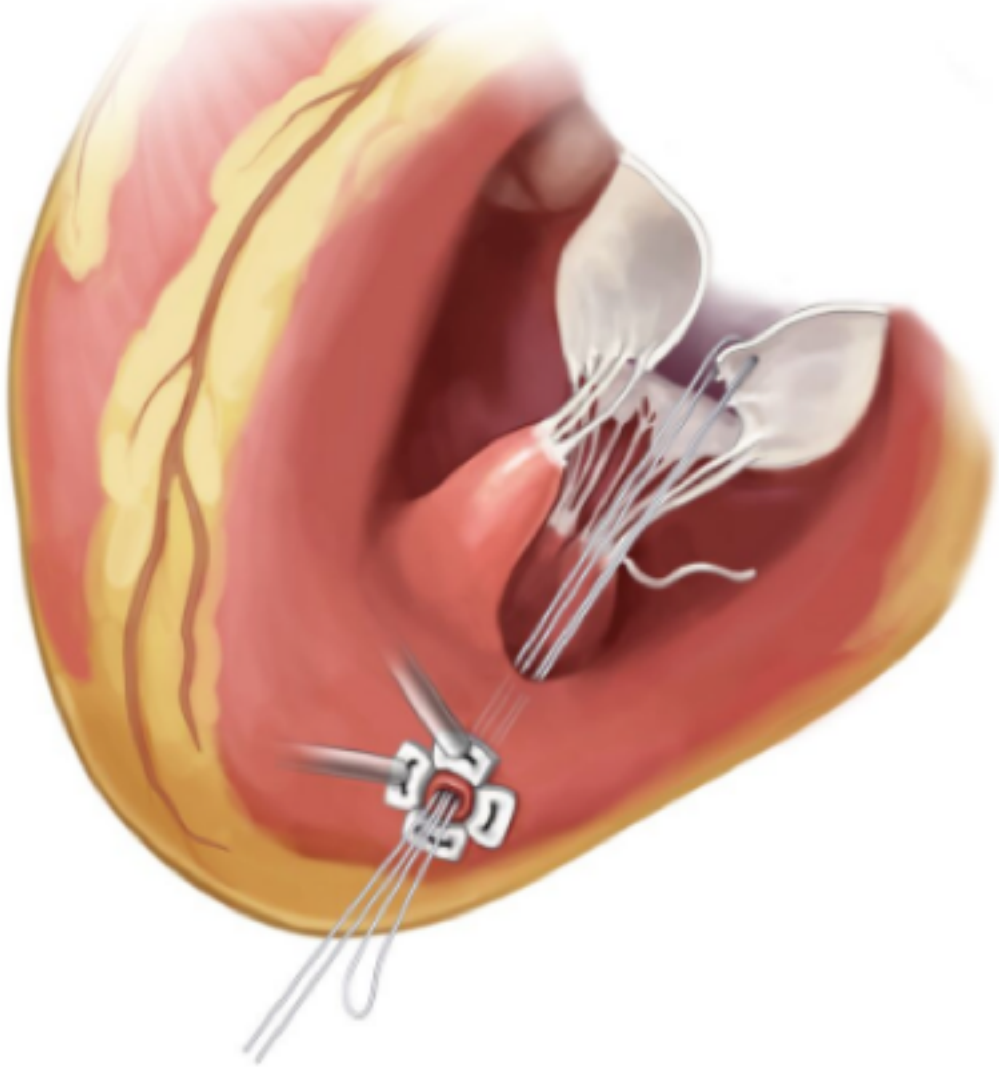
Four white lights on monitor correspond to leaflet coverage over the four fiber optic lights in the jaws of the device

Needle advancement





Placement of NeoChords



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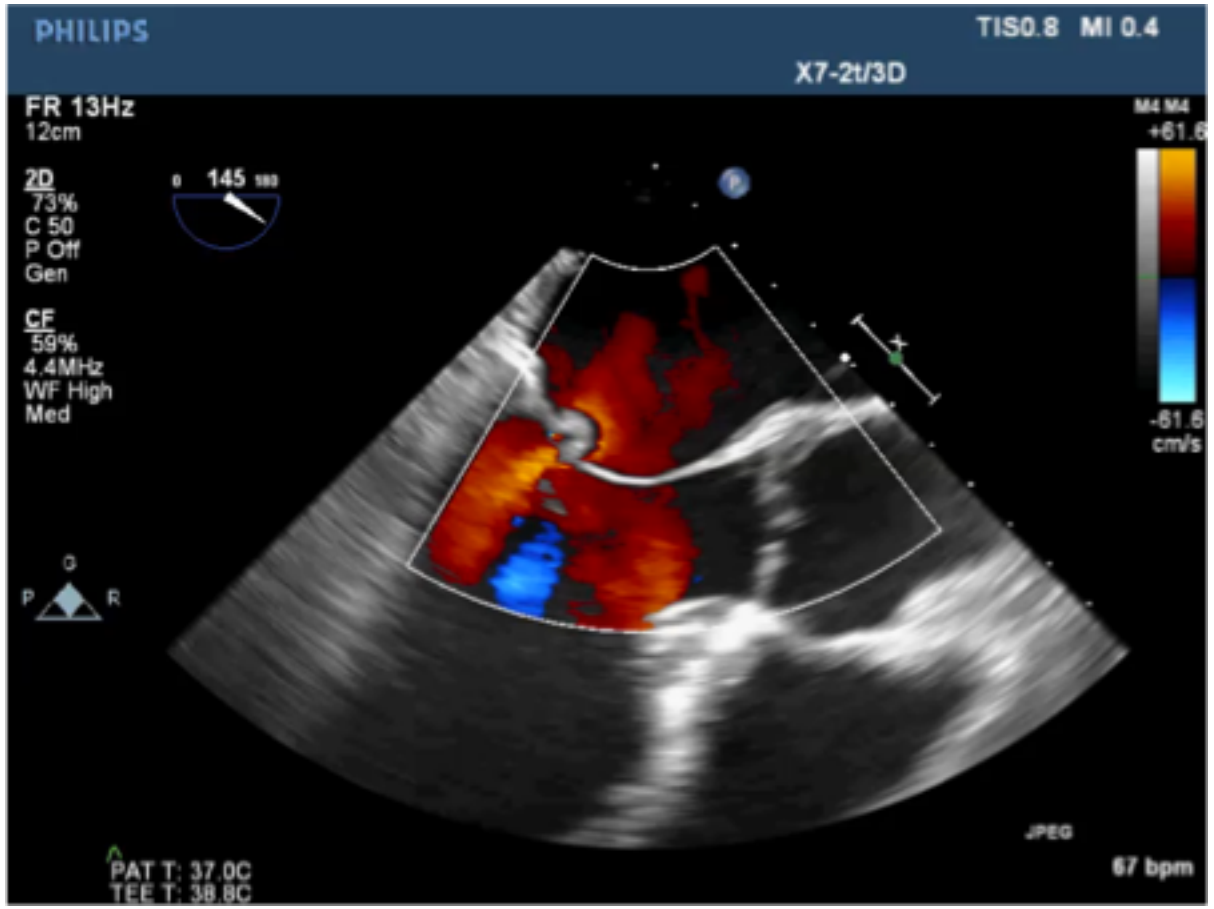
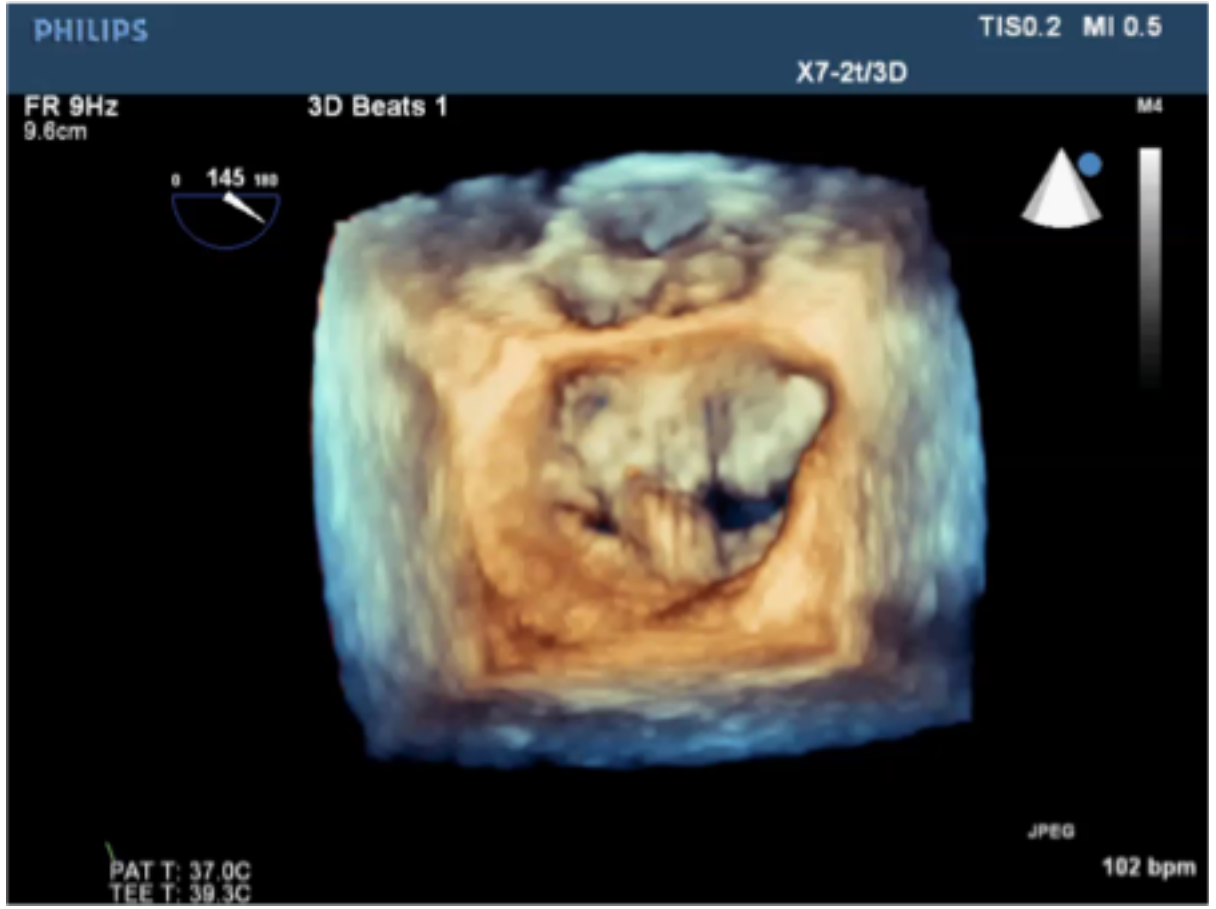
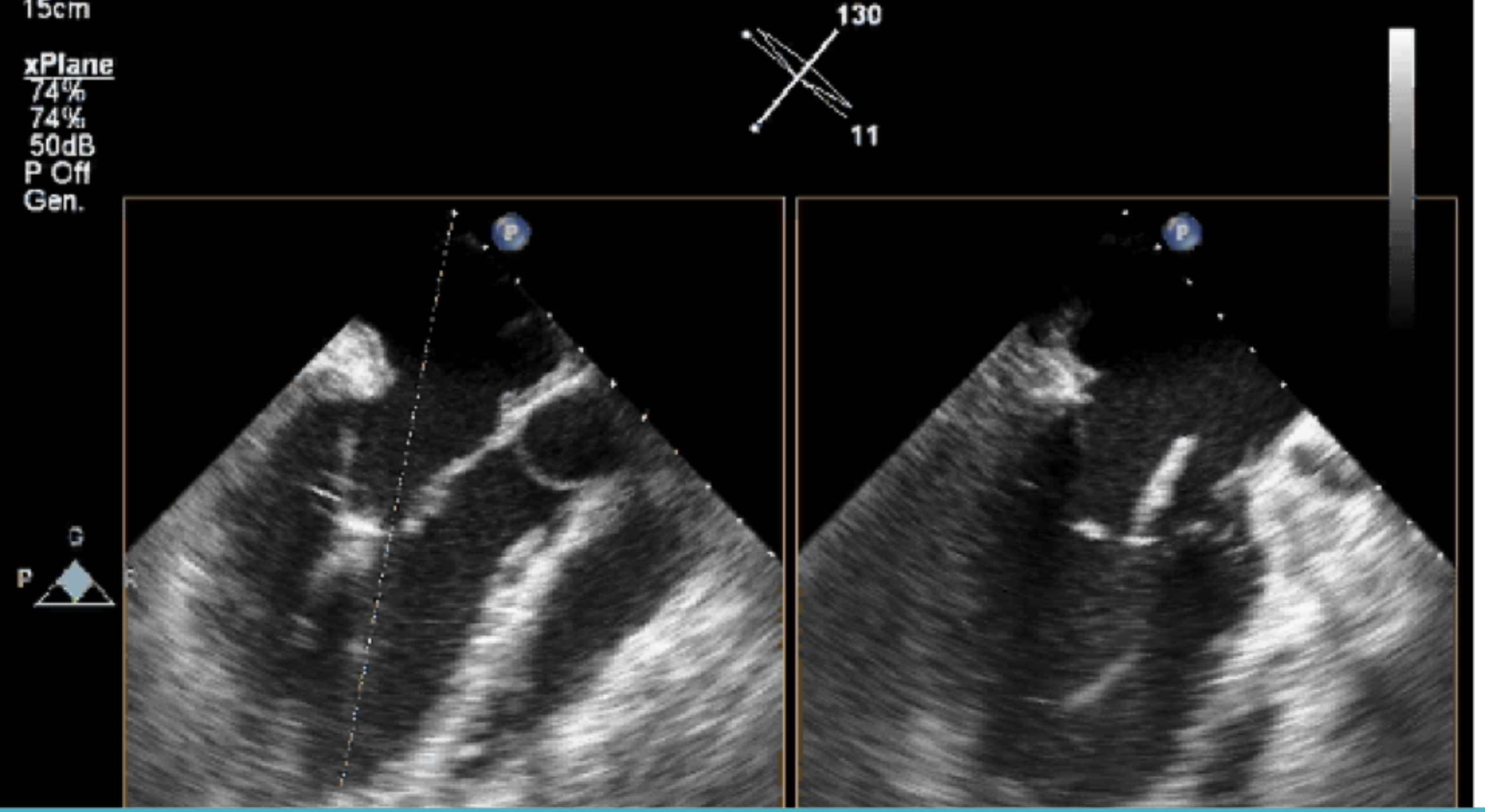
NeoChord Case Presentation 54 Year Old Male Patient with P2 Prolapse and Severe MR

Courtesy of Diana Zakarkaite, M.D.
Vilnius University Hospital Santaros Klinikos

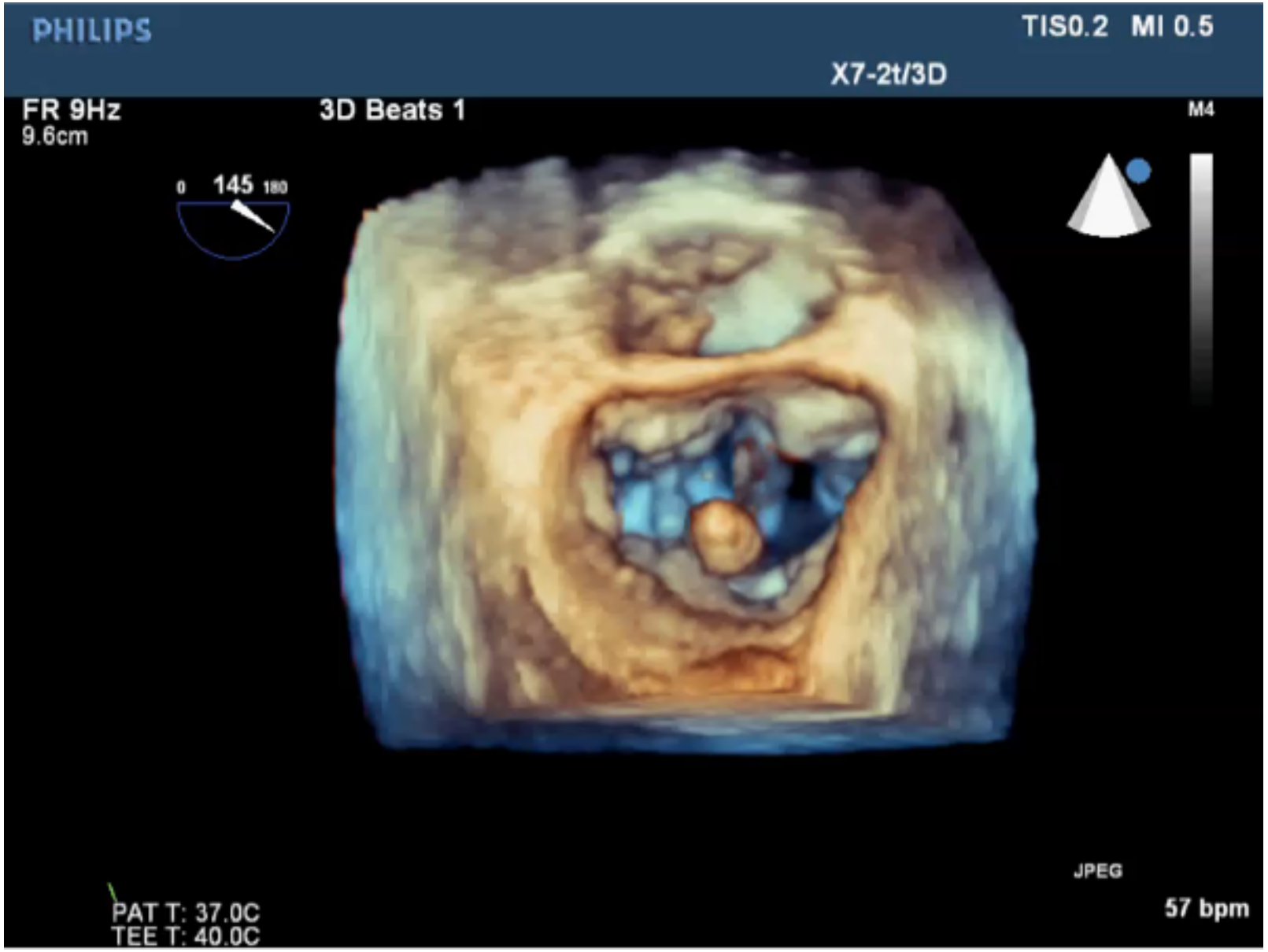
Pre-op echoes show P2 prolapse with single anterior-directed jet and severe MR



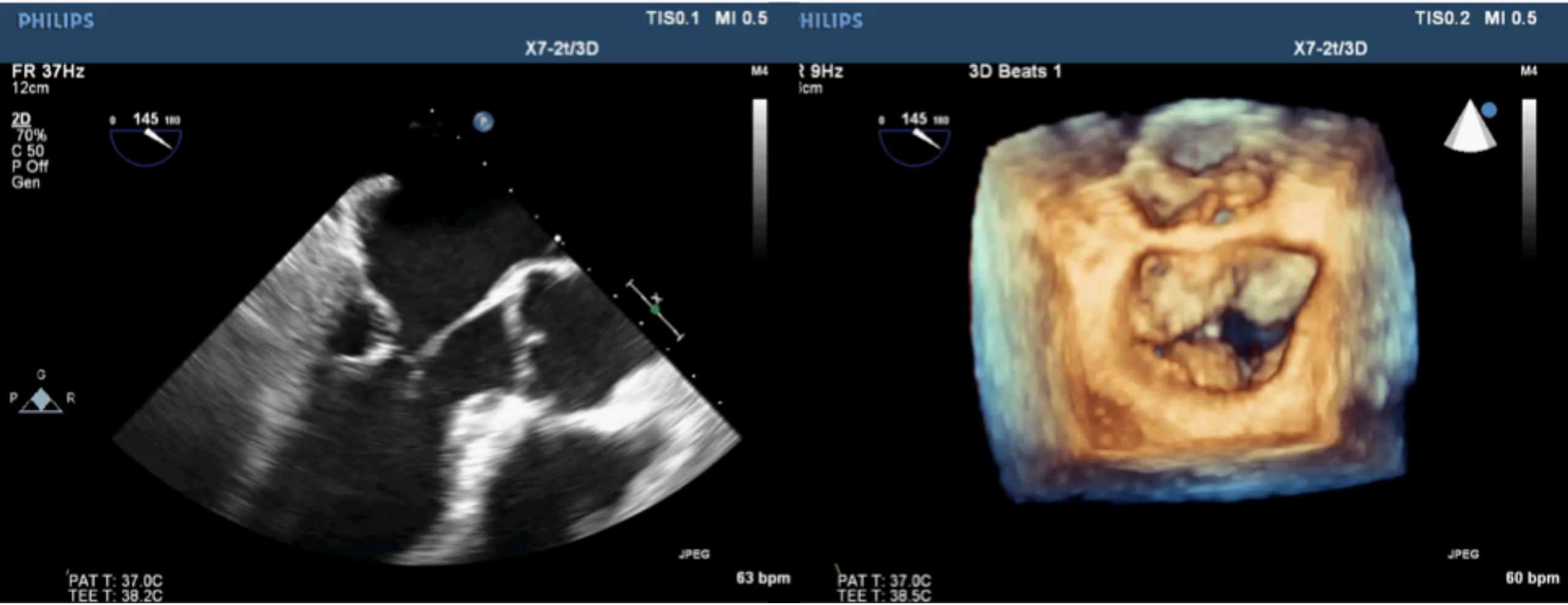



15cm
xPlane
74%
74%
50dB
P Off
Gen.
130
11
P
P
C
P

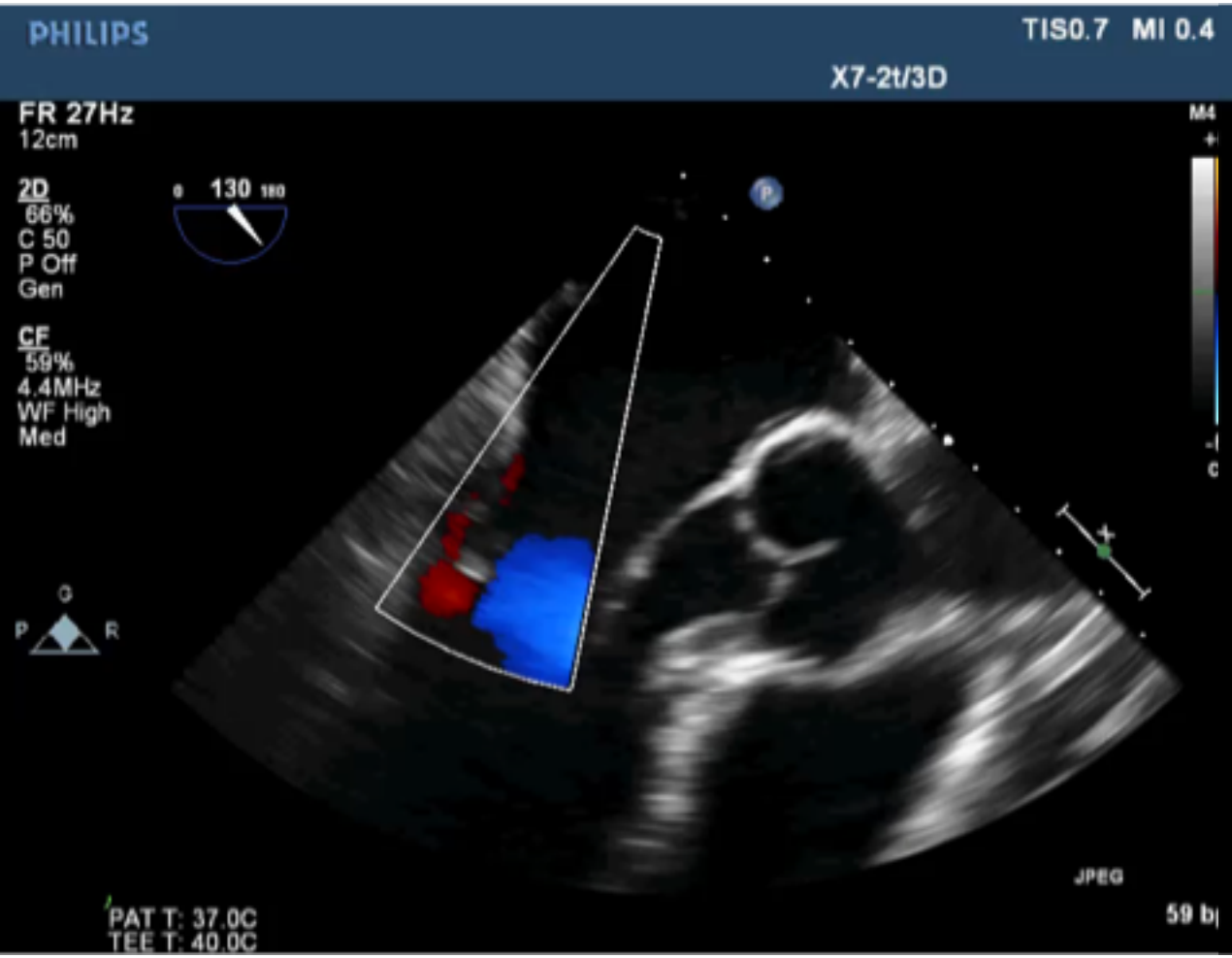
Capturing prolapsing P2 segment with device jaws

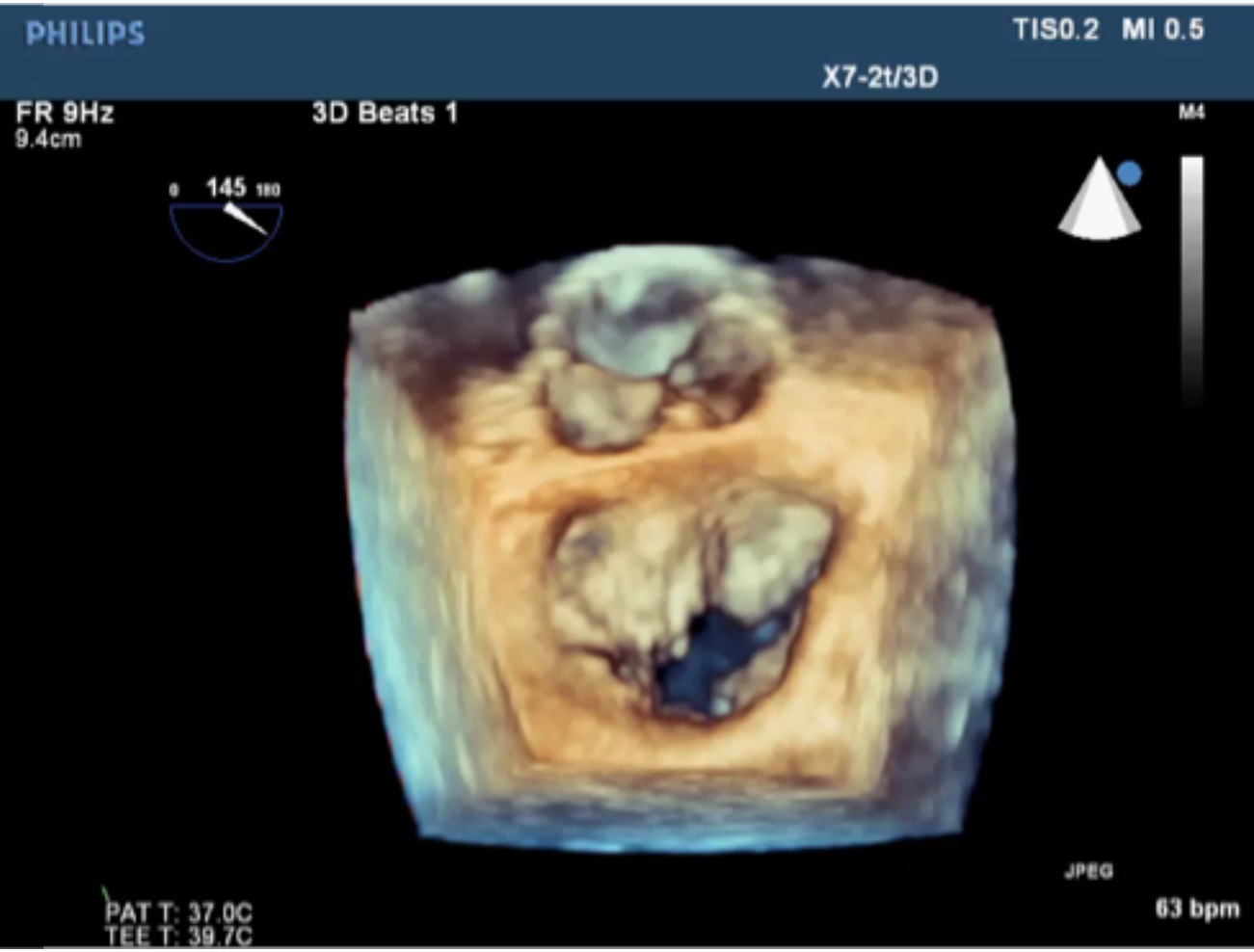


Tensioning NeoChord to pull prolapsing P2 segment down and re-establish coaptation

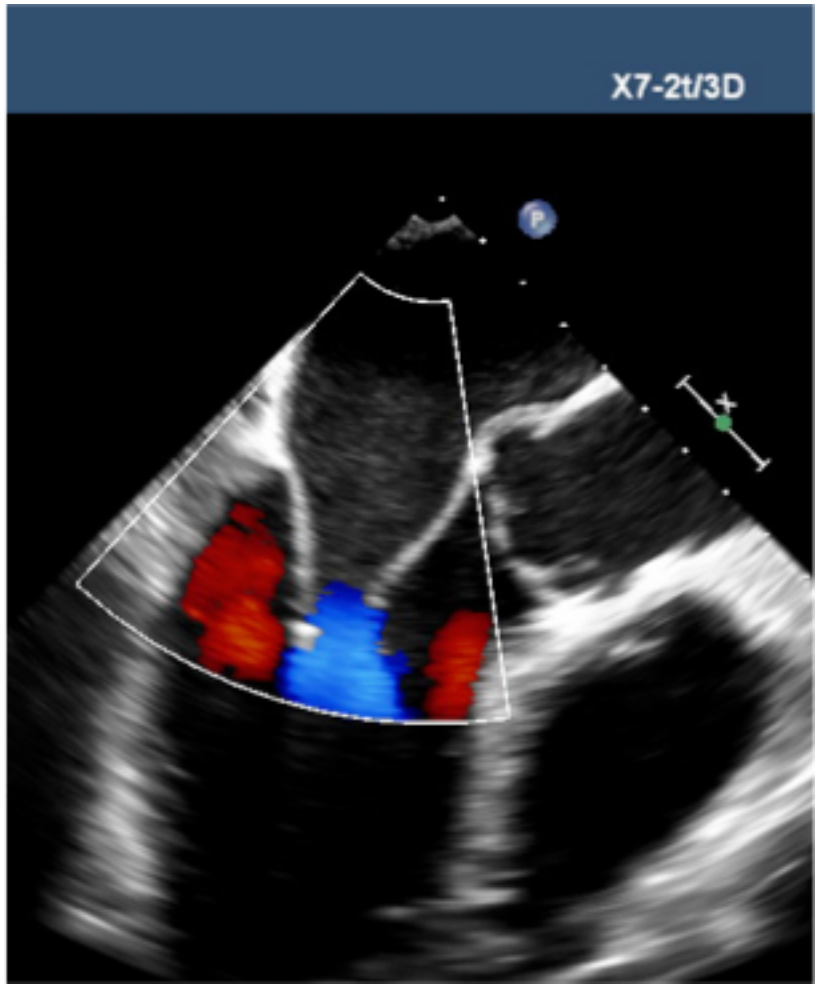


Post-op echoes following placement of 4 NeoChords achieving 4-5 mm of coaptation

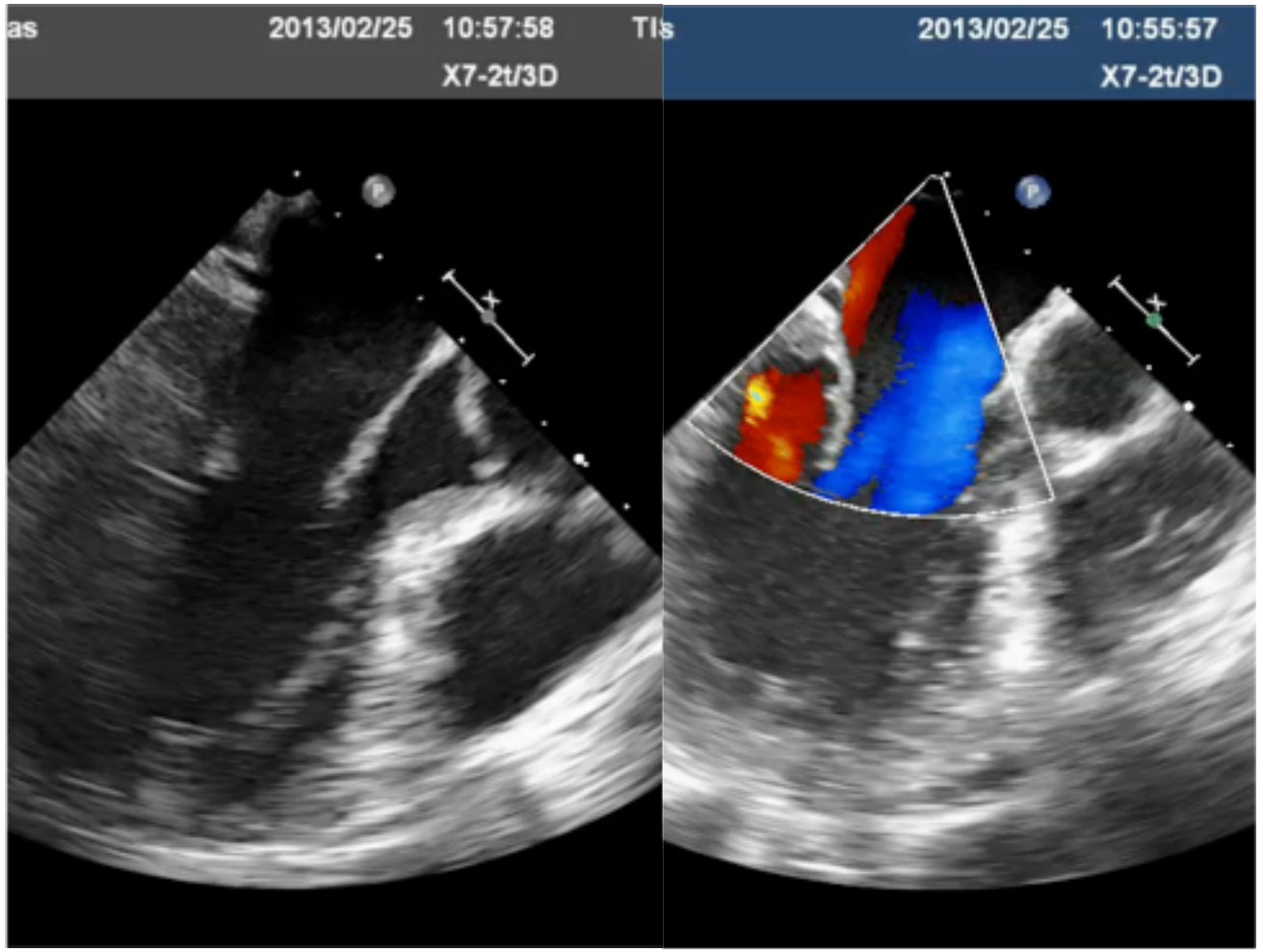




Assessment of post-procedural MR
Key concept: over-tensioning



NO!

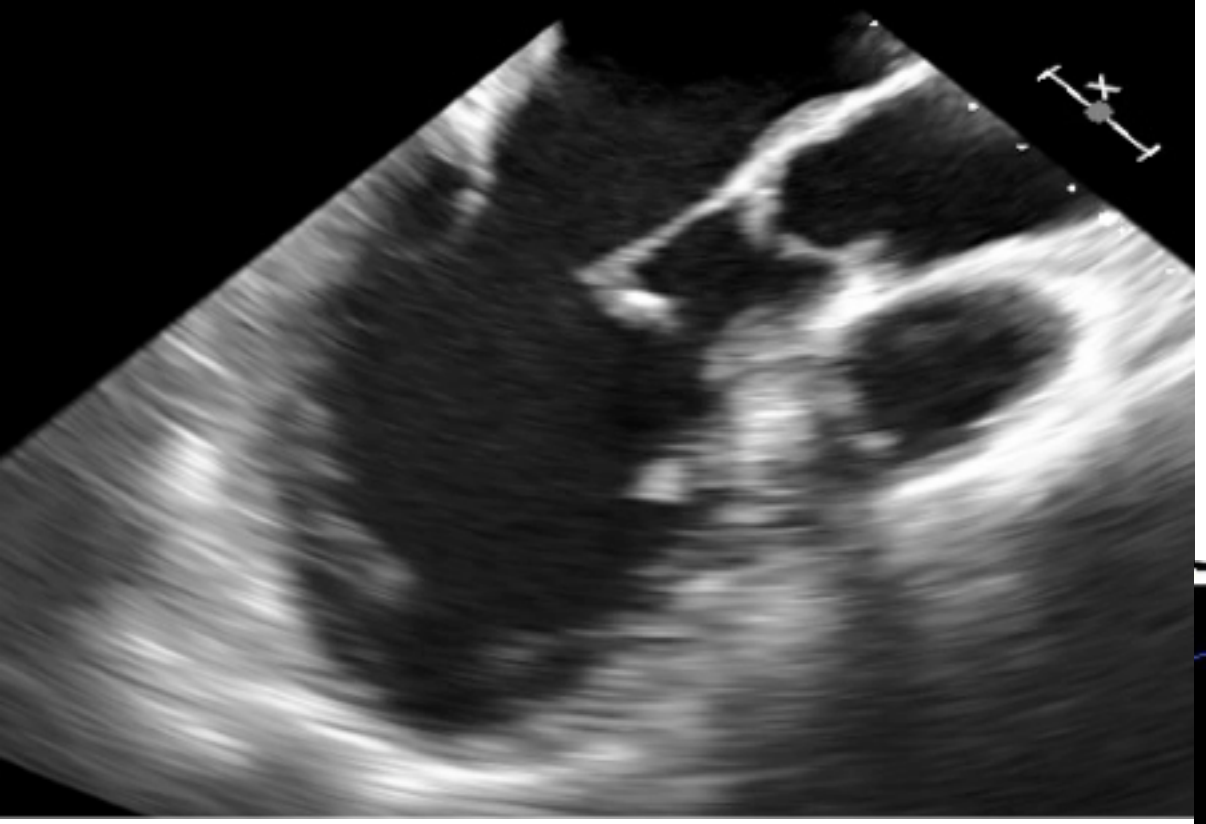


YES!

3 MAIN STEPS OF NEOCHORD OPERATION:

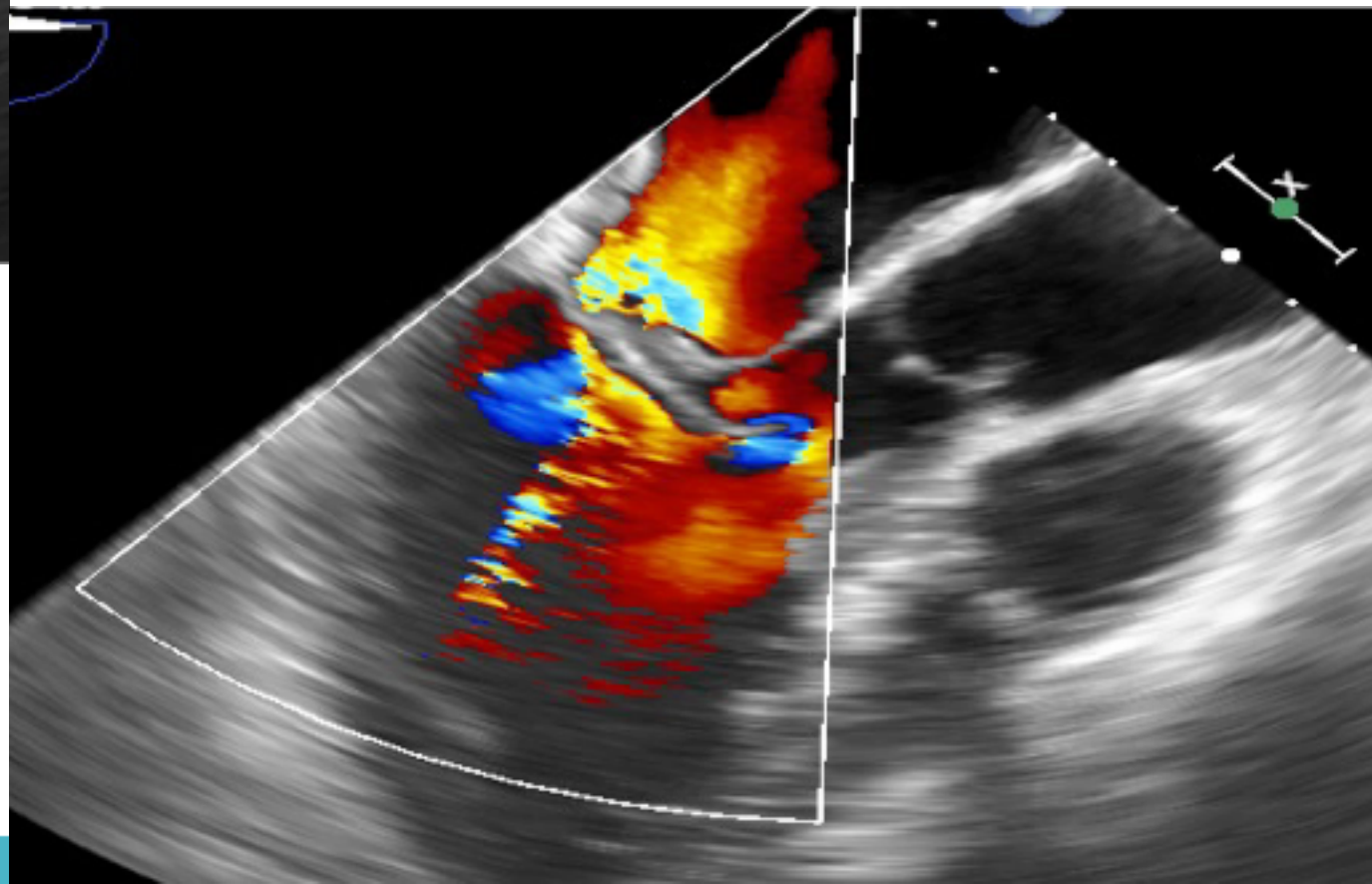
1. Choice of LV entry site
2. Number and placement of chordae on target leaflet
3. Final tensioning

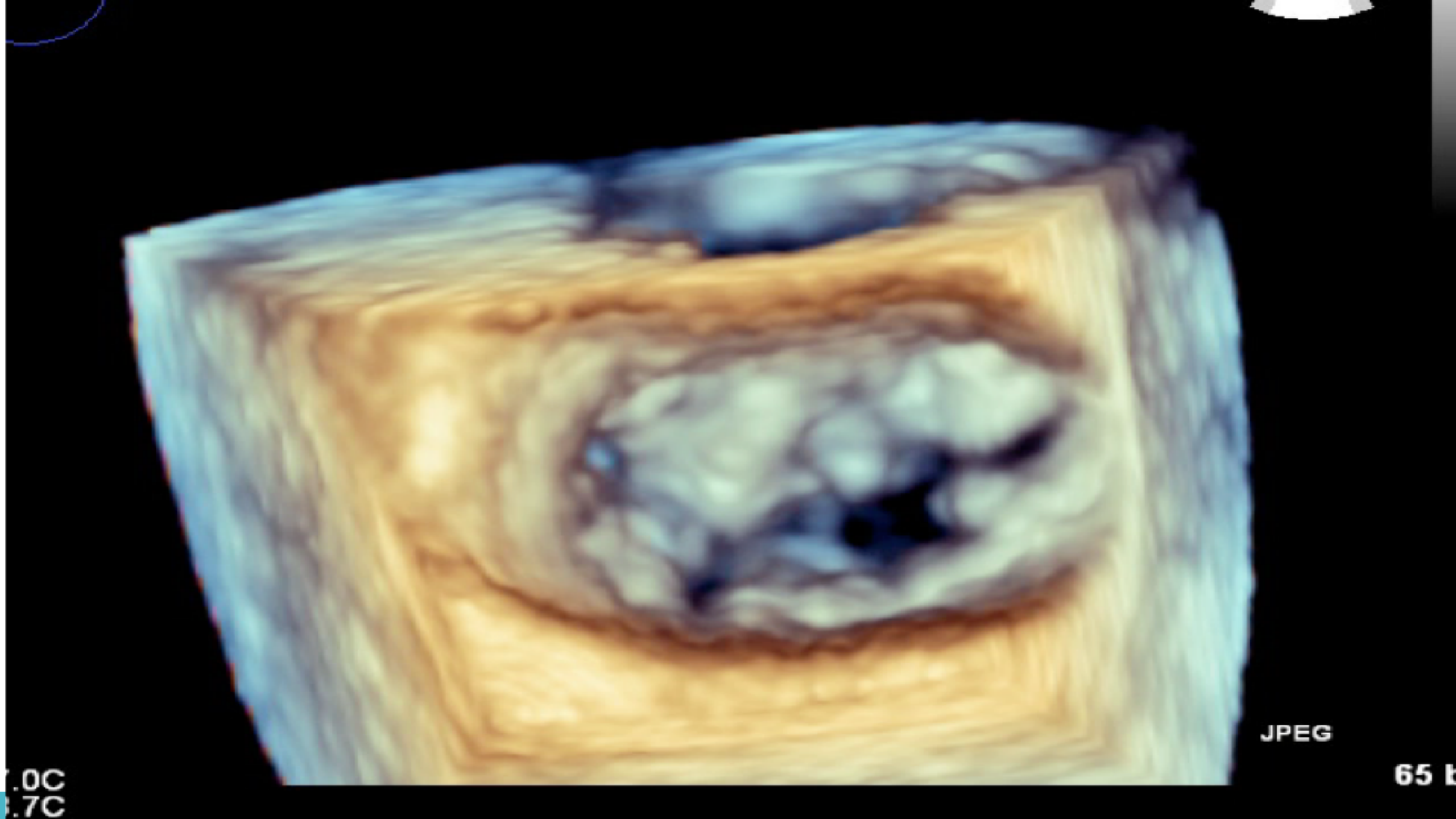
Each step has **100% relative importance** for the success of the procedure

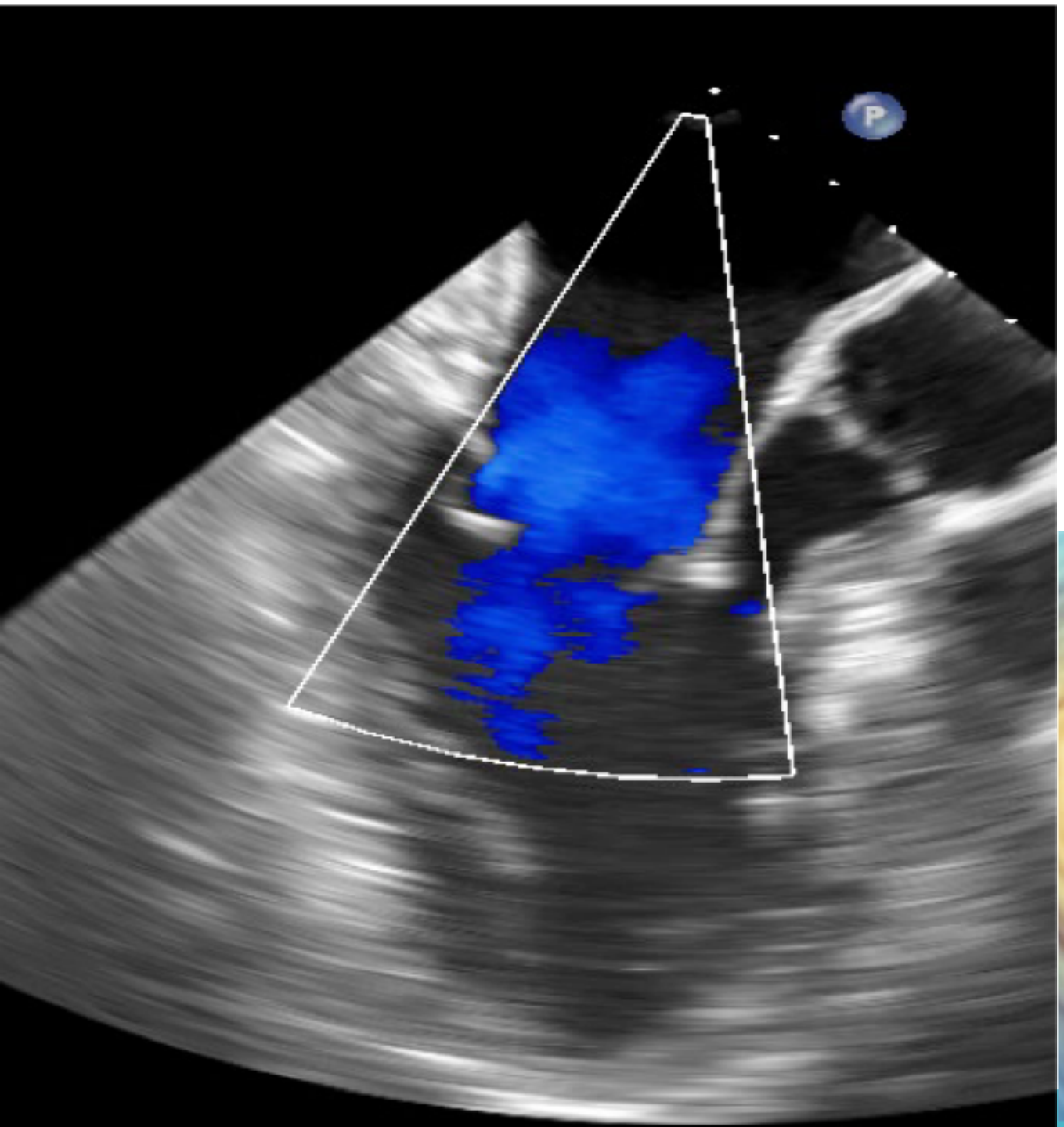


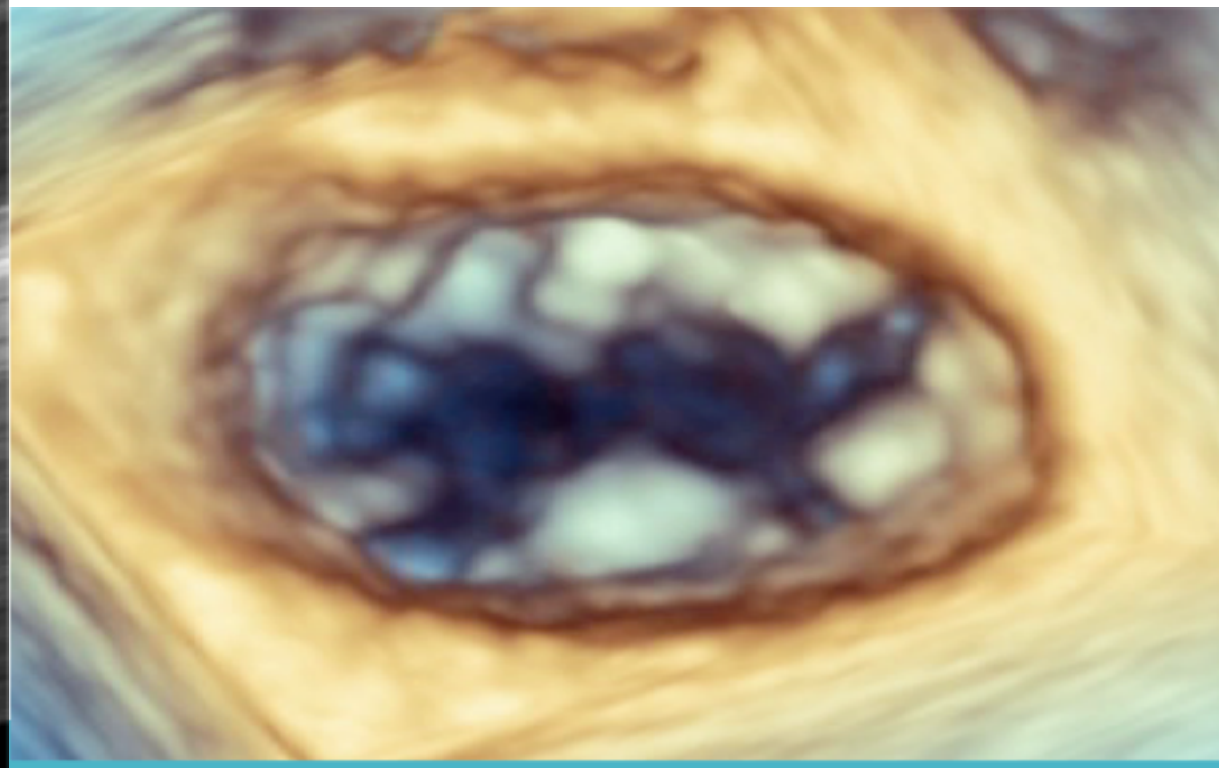
Not Only P2:

Also for Anterior leaflet prolapse/flail




JPEG
65 b



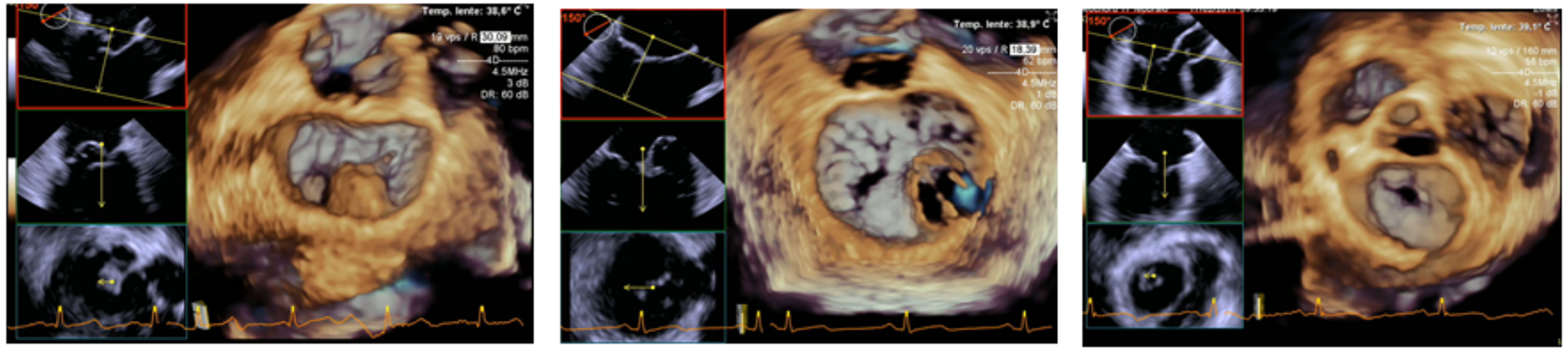


Worldwide activity: 1000+ cases

- **ITALY >300** (Torino, Padova, Milano, Brescia, Reggio Emilia, Bologna, Rapallo, Roma, Palermo, Bari,)
- **GERMANY 140** (Frankfurt, Leipzig, Trier, Goettingen, Duisburg, Munich, Hamburg, Dresden, Cologne, Aachen, Mainz)
- **LITHUANIA 95** (Vilnius)
- **TURKEY 80** (Ankara, Antalya, Istanbul area)
- **USA (FDA trial) 75 cases**
- **POLAND 45** (Warsaw)
- **FRANCE 24** (Bordeaux, Lyon, Nantes)
- **FINLAND 20** (Helsinki, Turku, Tampere)
- OTHER COUNTRIES: LATVIA, BELGIUM, SWITZERLAND, CANADA, NETHERLANDS, AUSTRIA, UK, ISRAEL, SPAIN (5-20 cases each)

RESULTS AND DURABILITY are dependent on Preoperative Mitral Valve Morphology

- **TYPE A:** Isolated central posterior leaflet prolapse/flail (P2)
- **TYPE B:** Posterior multisegment prolapse/flail
- **TYPE C:** anterior, bileaflet disease, presence of annular/leaflet calcifications and/or paracommissural

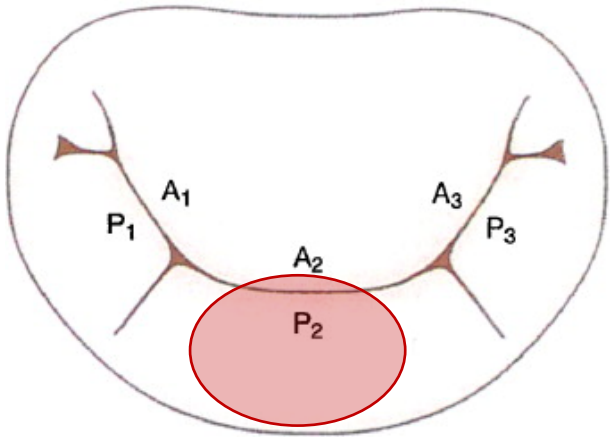


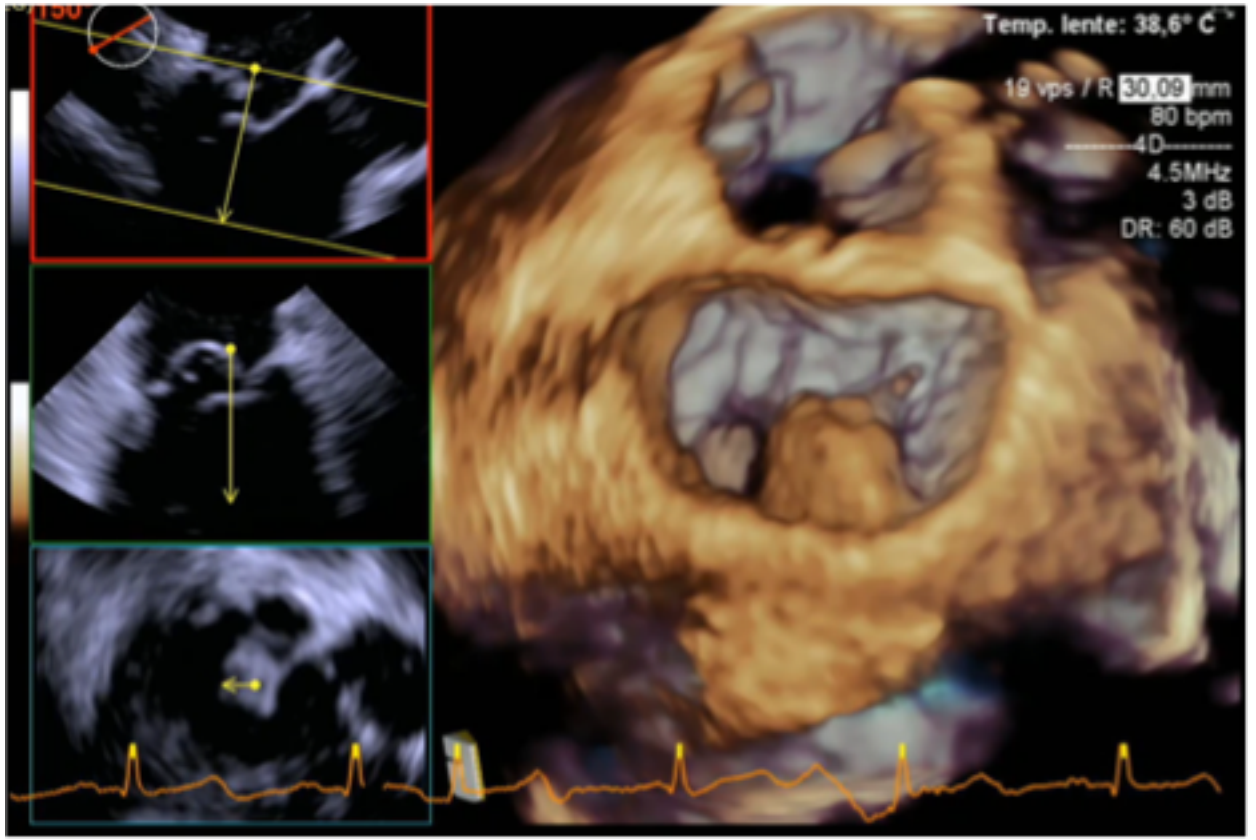
Colli et al, Interact Cardiovasc Thorac Surg 2015

Preoperative TEE

MV Anatomical type definition

TYPE A

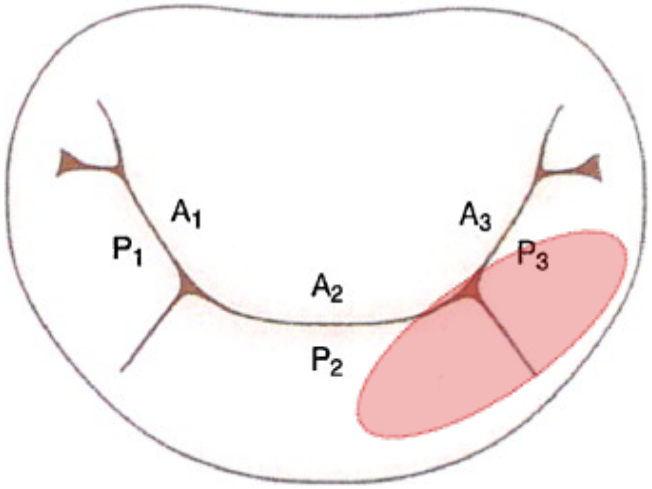


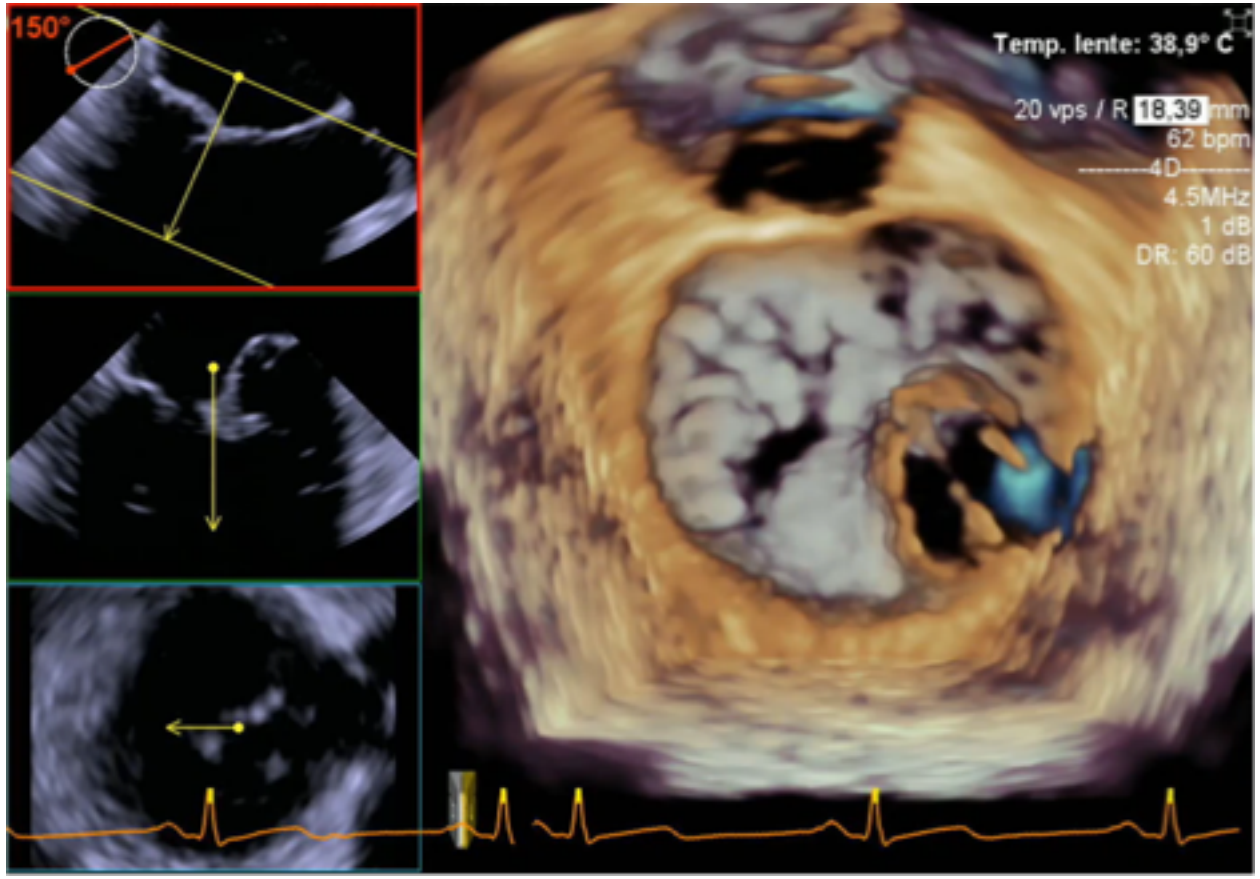


Preoperative TEE

MV Anatomical type definition

TYPE B

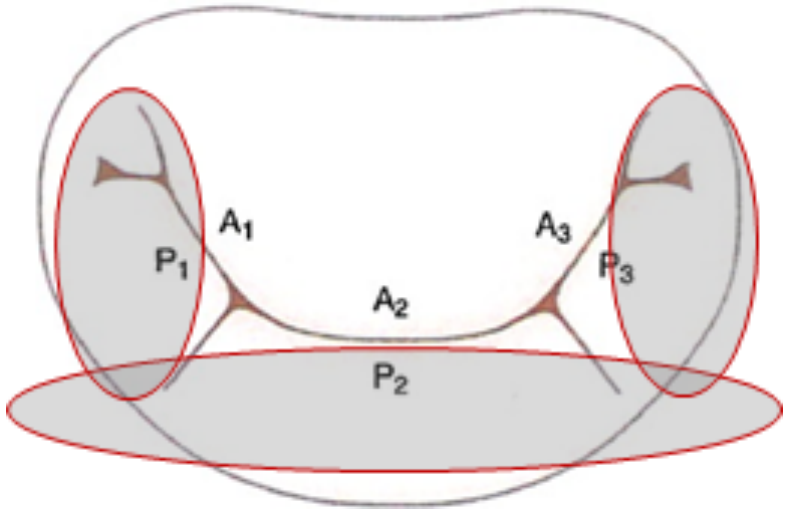


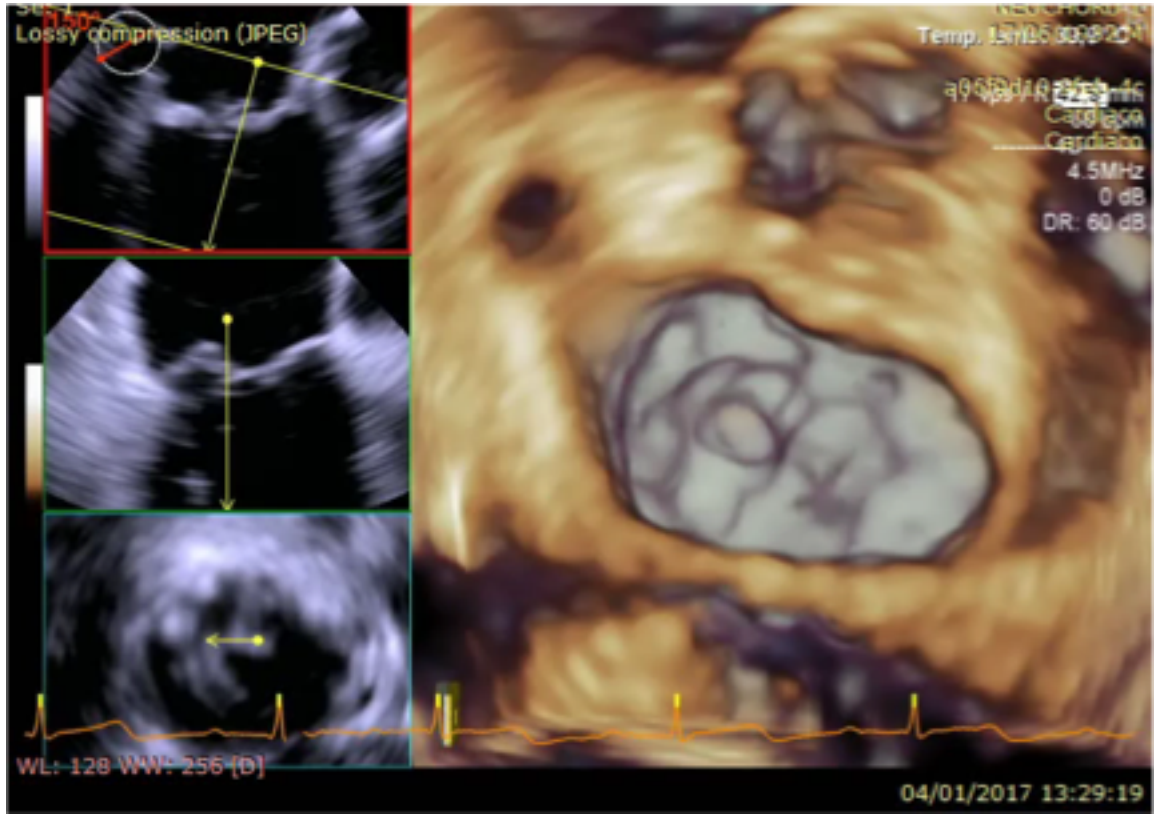


Preoperative TEE

MV Anatomical type definition

TYPE C





Seven Centers Enrolled 213 Patients, 2013-2016

An early European experience with transapical off-pump mitral valve repair with NeoChord implantation†

Andrea Colli[a,*], Erica Manzan[a], Audrius Aidietis[b], Kestutis Rucinskas[b], Eleonora Bizzotto[a], Laura Besola[a], Nicola Pradegan[a], Demetrio Pittarello[a], Vilius Janusauskas[b], Diana Zakarkaite[b], Agne Drasutiene[b], Arturas Lipnevicius[b], Bernhard C. Danner[c], Horst Sievert[d], Laura Vaskelyte[d], Nalan Schnelle[d], Stefano Salizzoni[e], Massimo Marro[e], Mauro Rinaldi[e], Katarzyna Kurnicka[f], Kristof Wrobel[g], Mariano Ceffarelli[h], Carlo Savini[h], Davide Pacini[h] and Gino Gerosa[a]

[a] Cardiac Surgery Unit, Department of Cardiac, Thoracic, and Vascular Sciences, University of Padua, Padua, Italy
[b] Department of Cardiovascular Medicine, Vilnius University, Vilnius, Lithuania
[c] Department of Thoracic and Cardiovascular Surgery, University Medical Center, Georg-August University, Göttingen, Germany
[d] CardioVascular Center Frankfurt CVC, Sankt Katharinen, Frankfurt, Germany
[e] Division of Cardiac Surgery, Department of Surgical Sciences, Città della Salute e della Scienza di Torino, University of Turin, Turin, Italy
[f] Department of Internal Medicine and Cardiology, Medical University of Warsaw, Warsaw, Poland
[g] Department of Cardiac Surgery, Medicover Hospital, Warsaw, Poland
[h] Department of Cardiovascular Surgery, Sant'Orsola-Malpighi Hospital, Bologna University, Bologna, Italy

Eur J Cardiothorac Surg 2018; doi:10.1093/ejcts/ezy064

Secondary Analysis of Results by Anatomical Group Was Performed

A secondary analysis was performed by comparing the primary end point among the anatomical groups (A, B and C) defined according to the conventional MV surgery as follows [1]. Patients were stratified according to the preoperative 3D TOE assessment of MV morphology: 'Type A', isolated central posterior leaflet prolapse/flail; 'Type B', posterior multisegment prolapse/flail and 'Type C', anterior, bileaflet or paracommissural disease with or without leaflet and annular calcifications.

Patient Demographics and Preoperative Echocardiographic Characteristics

Table 1: Patient demographics and preoperative echocardiographic data

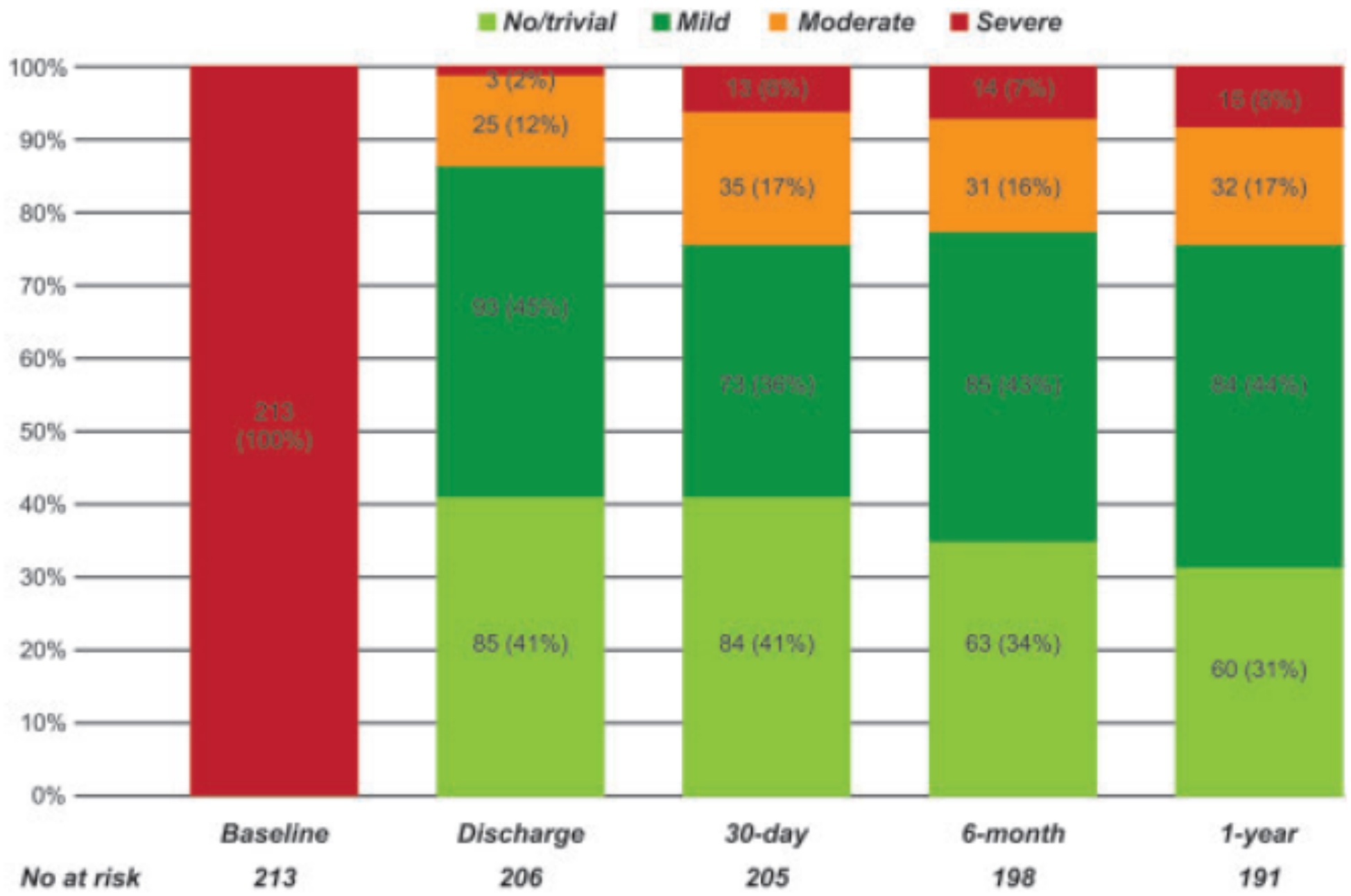
	Median (I–III quartile), *n* (%) or mean ± SD
Age (years)	68 (56–77)
Male	153 (71.8)
EuroSCORE II (%)	1.8 ± 2.5
STS-PROM MV repair score (%)	1.5 ± 2.1
Arterial hypertension	126 (59.1)
Chronic obstructive pulmonary disease	20 (9.4)
Diabetes mellitus Type II	13 (6.1)
Associated ischaemic cardiomyopathy	32 (15)
Previous cardiac Surgery	11 (5.2)
Previous percutaneous coronary intervention	17 (8)
Previous stroke	1 (0.5)
Malignancy	23 (10.8)
Glomerular filtration rate (ml/min)	75.8 (55.3–98.5)
NYHA functional class	
I	14 (6.6)
II	92 (43.2)
III	101 (47.4)
IV	6 (2.8)
MR grade	
Absent/trace	
Mild	
Moderate	
Severe	213 (00)
Leaflet involvement	
Posterior mitral leaflet	193 (90.6)
Anterior mitral leaflet	11 (5.2)
Bileaflet	9 (4.2)
Leaflet prolapse	74 (34.7)
Leaflet flail	139 (65.3)
Anatomical MV type	
A	82 (38.5)
B	98 (46)
C	33 (15.5)

Procedural and 30-Day Outcomes

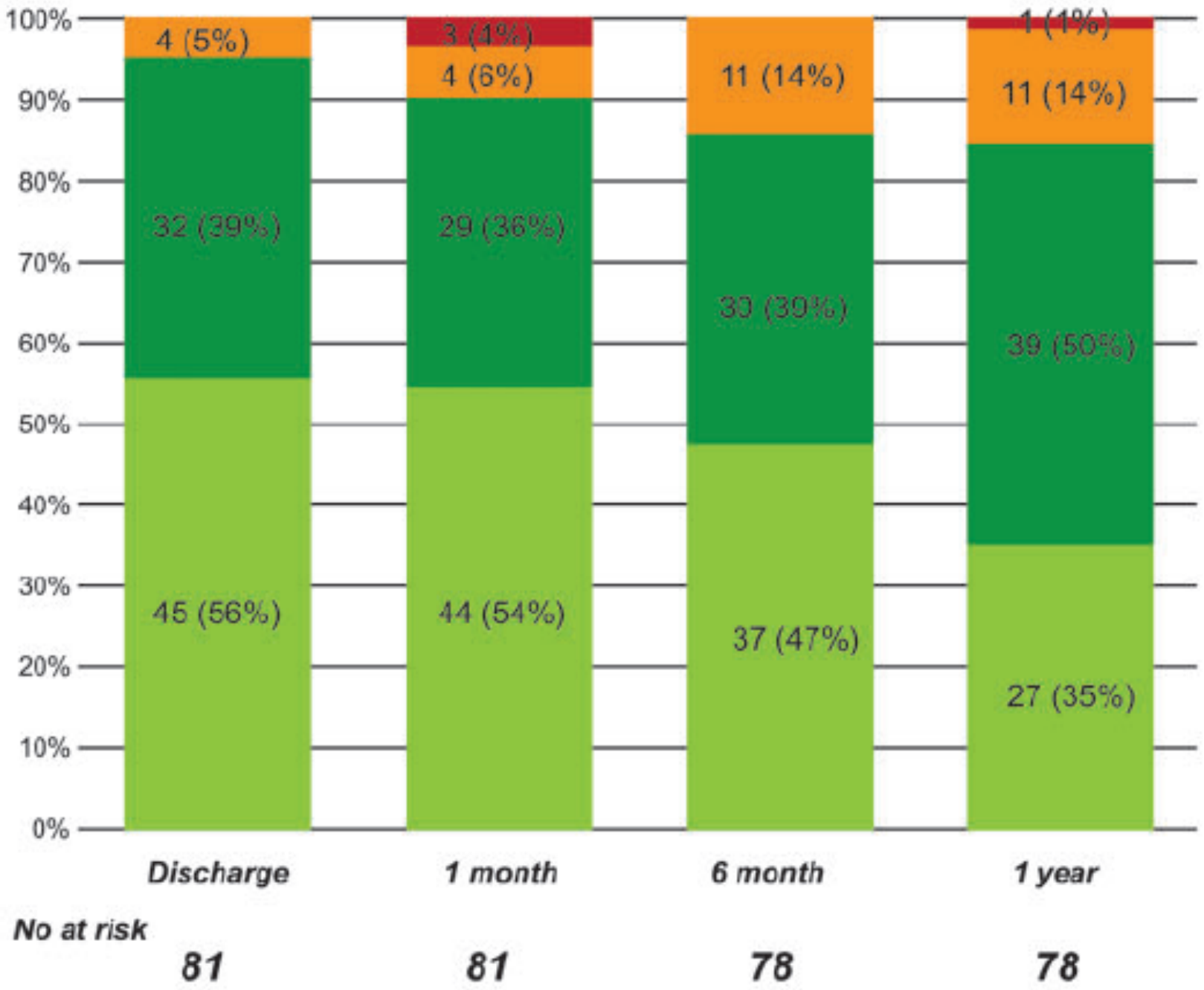
	Median (I–III quartile) or *n* (%)
Neochordae in place (*n*)	4 (3–4)
0	1 (0.5)
2	8 (3.8)
3	73 (34.3)
4	79 (37.1)
5	34 (16)
6	12 (5.6)
7	3 (1.4)
8	2 (0.9)
9	1 (0.5)
Neochordae implantation attempts (*n*)	4 (3–5)
Operative time (min)	130 (120–155)
Conversion to conventional surgery	4 (1.9)
MV repair	2 (0.9)[a]
MV replacement	2 (0.9)

Procedural success	206 (96.7)
Transient ischaemic attack[b]	1 (0.5)
Stroke[b]	
Acute myocardial infarction[b]	2 (1)
Vascular complications[b]	1 (0.5)
Acute kidney injury[b]	14 (6.7)
Stage I (creatinine increase >150–199%)	9 (4.3)
Stage II (creatinine increase >200–299%)	3 (1.4)
Stage III (creatinine increase >300%)	2 (1)
Need for CVVH	2 (1)
Conduction disturbances[b]	17 (8.1)
Transient	17 (8.1)
Permanent	
Need for permanent PM implantation	
New-onset atrial fibrillation[b]	47 (22.5)
Paroxysmal	40 (19.2)
Persistent	7 (3.3)

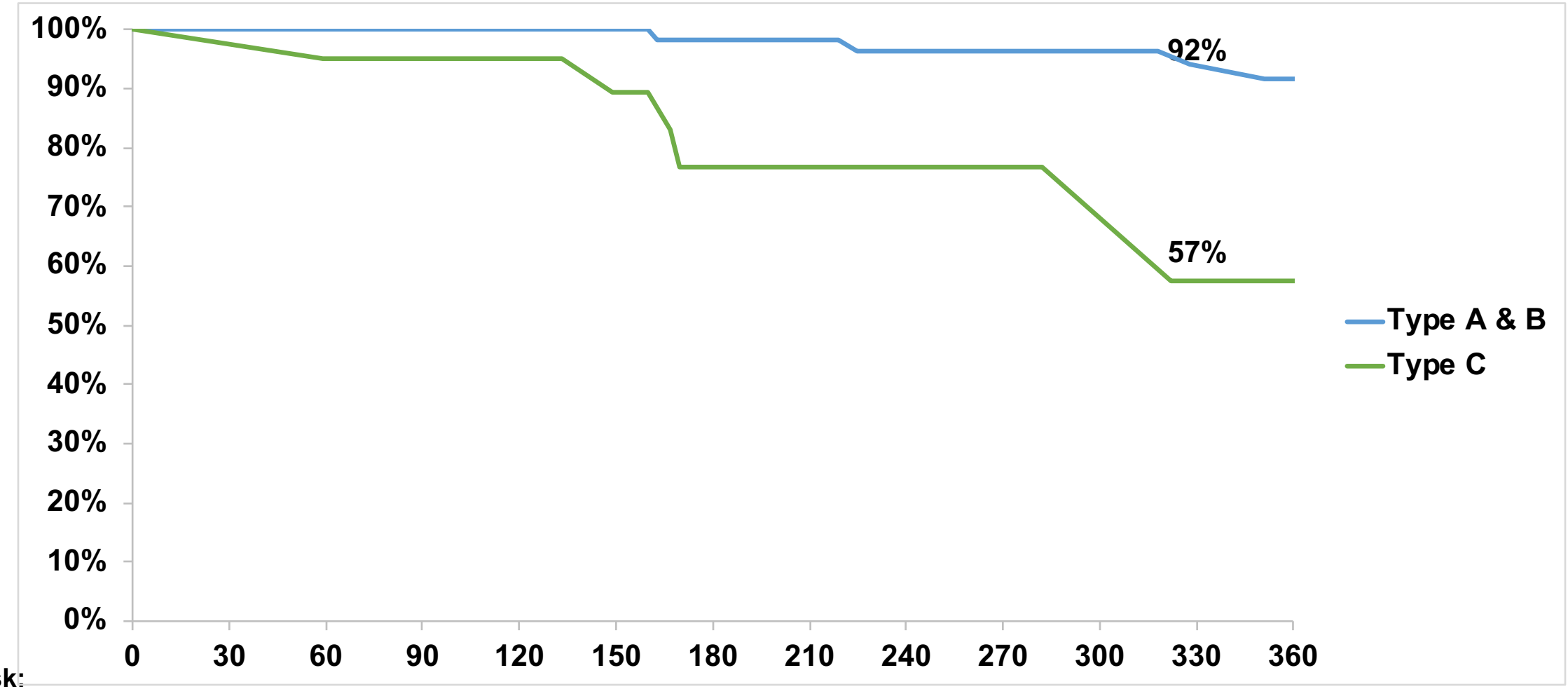
Overall Degree of MR



TYPE A
Degree of MR



Type A & B vs. Type C – DURABILITY



At Risk:												
Type A & B:	68	68			57				38			
Type C:	20	20			11				3			

**Date set as of 1-Jul-15

CONCLUSIONS

This study demonstrates the safety and clinical benefits of the NeoChord repair are sustained up to 1-year follow-up as measured by the composite end point. Given the low complication rate and high surgical success rate, the NeoChord repair procedure should be considered a possible therapeutic option to treat patients presenting posterior leaflet prolapse/flail (Type A and B anatomies) and anterior leaflet disease if adequate MV tissue over-riding is present. In cases of paracommissural disease and/or calcifications of the annulus/leaflets, the NeoChord repair is not recommended. Future detailed echocardiographic studies with larger and longer series of patients—studies that are already ongoing—will lead to more precise identification of anatomical indications for isolated ringless NeoChord procedures and COMBO (combination) transcatheter MV repair procedures that will combine leaflet and annular therapies [15].

NeoChord **Five-Year** Durability Data on Initial Patients (Leipzig Heart Center)

Good Five-Year Durability of Transapical Beating Heart Off-Pump Mitral Valve Repair With Neochordae[1]

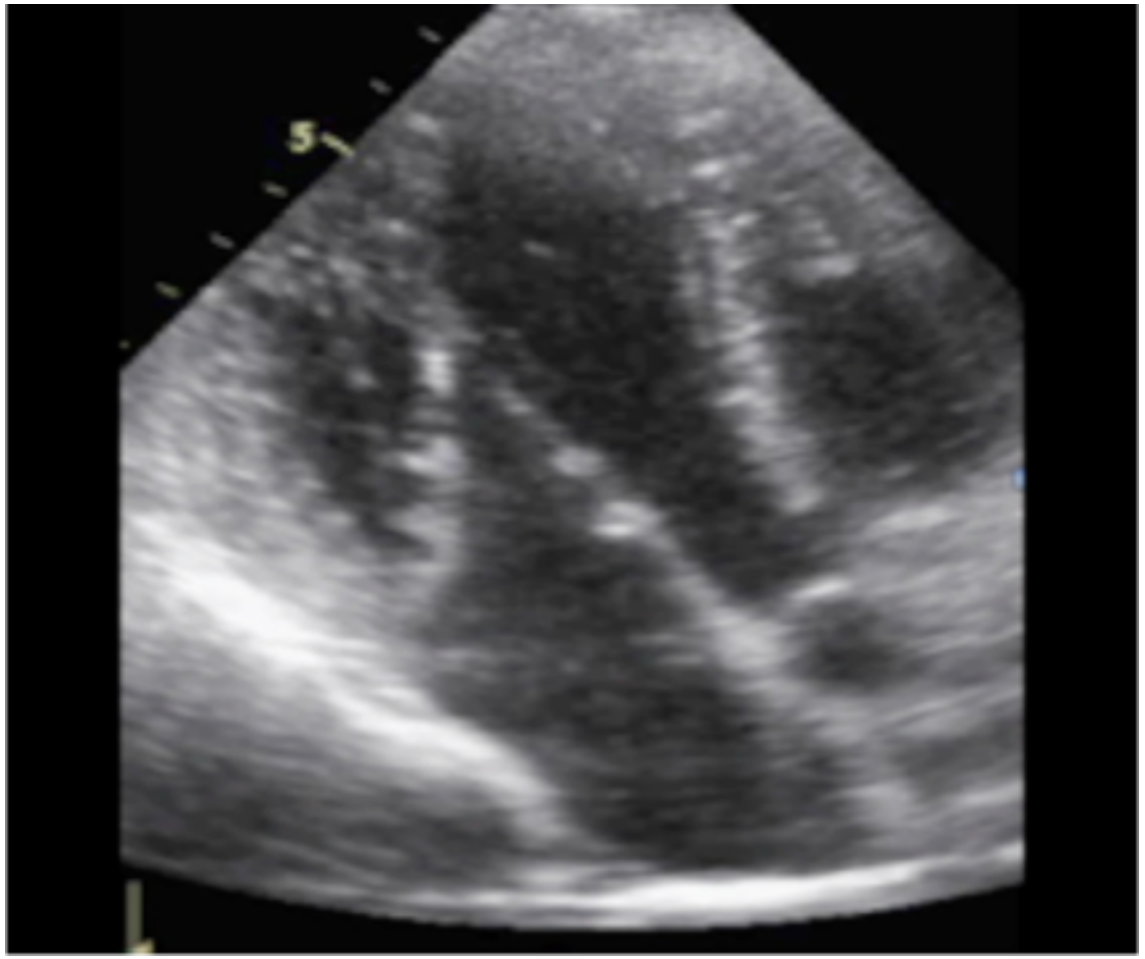
"In select patients MV repair using the NeoChord system results in very good long term results without recurrent prolapse, MR, or annular dilatation."[1]

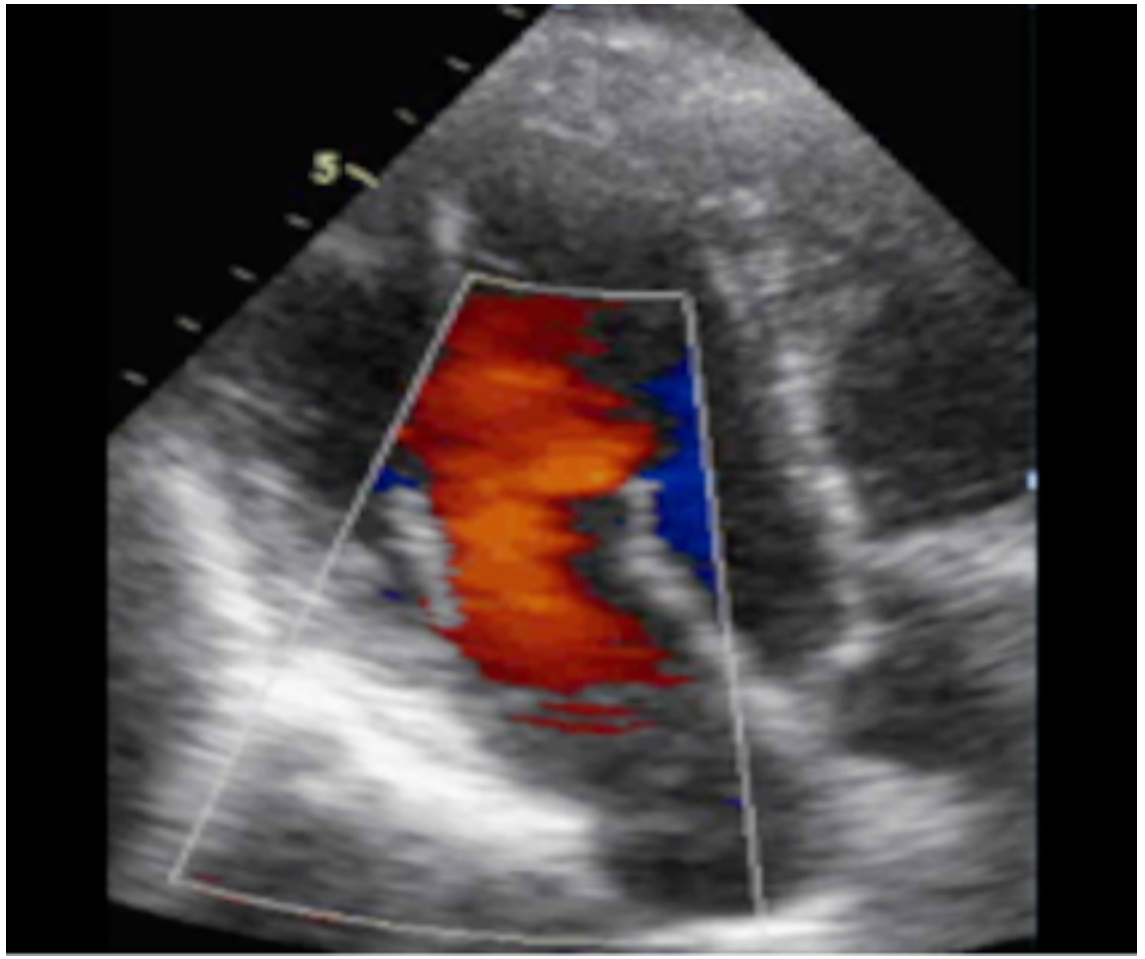
- Mitral annular dilatation was moderate at the time of surgery and did not show further increase over time

[1]Kiefer P, Meier S, Noack T, Borger MA, Ender J, Hoyer A, Mohr FW, Seeburger J, Good Five-Year Durability of Transapical Beating Heart Off-Pump Mitral Valve Repair With Neochordae, *The Annals of Thoracic Surgery* (2018), doi: 10.1016/j.athoracsur.2018.01.092.

UNIVERSITÄT LEIPZIG
HERZZENTRUM

Surg. in 2010; **5 Years F/U**

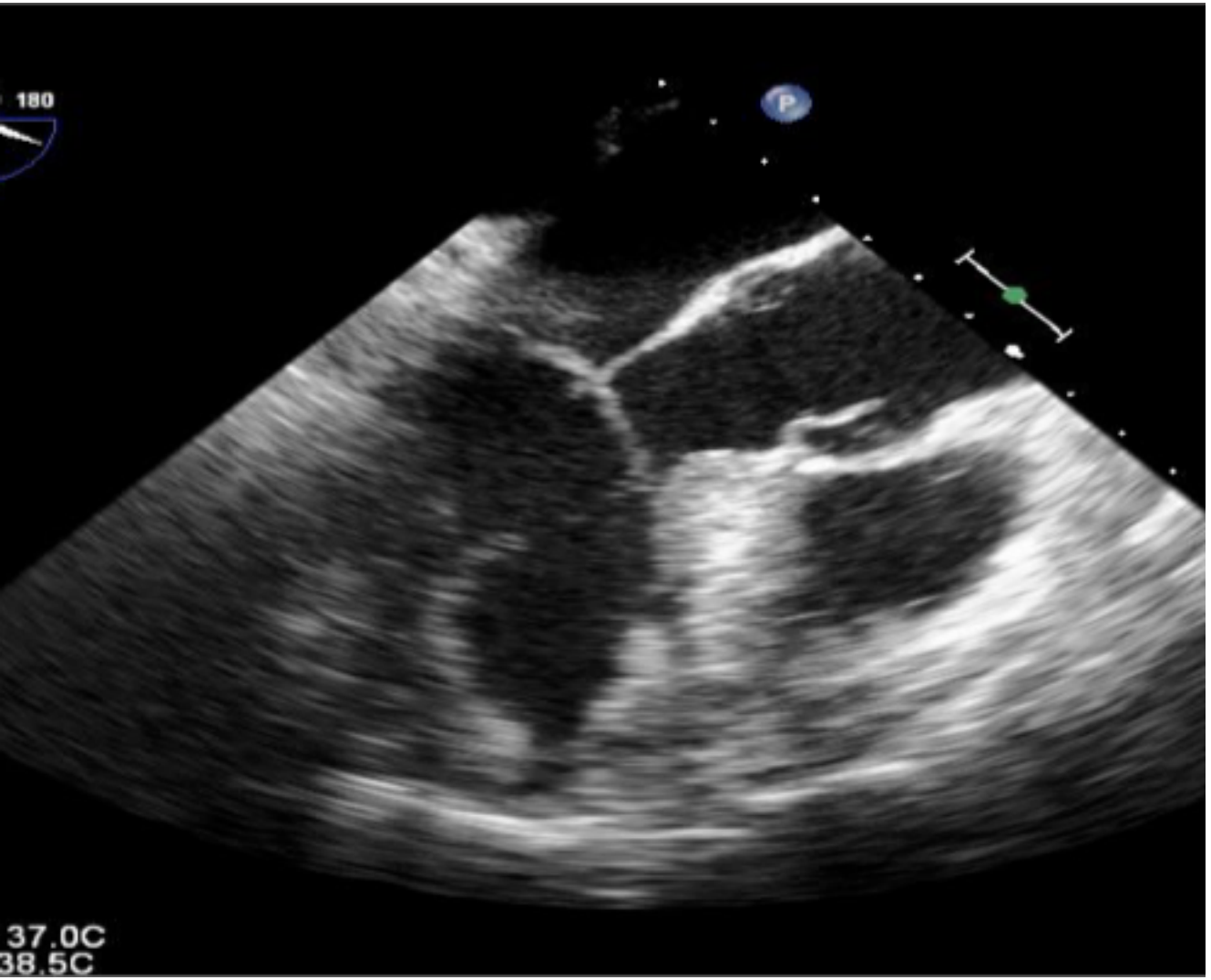


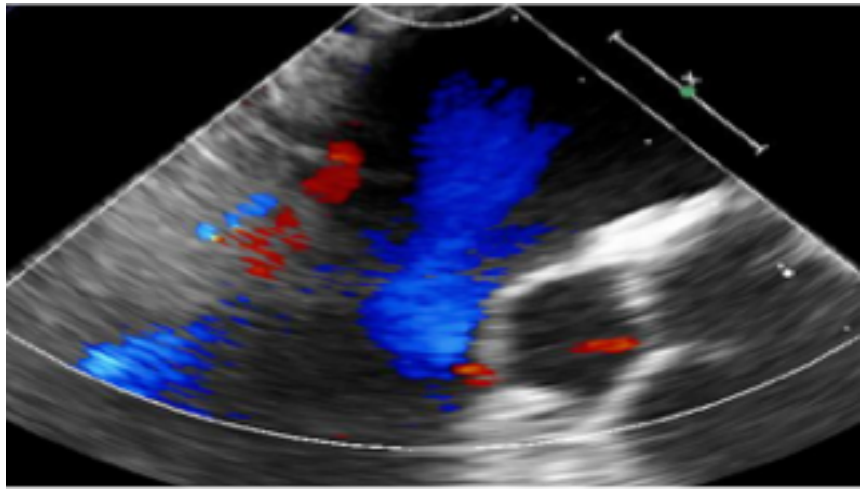


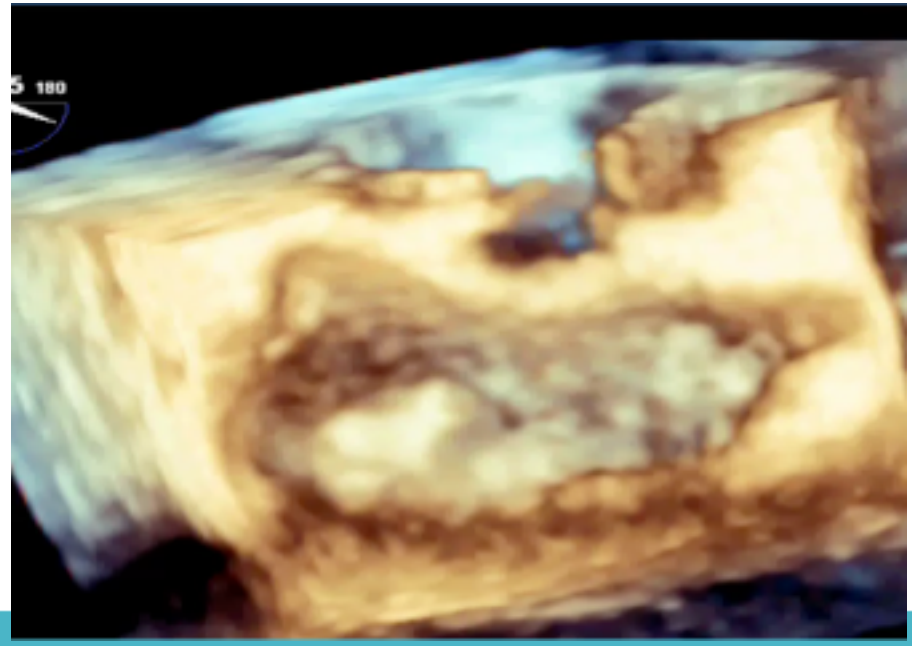
62 y old female, P2 prolapse, no re-admission, no recurrent MR
Courtesy: Dr. Joerg Seeburger

NeoChords to treat SAM: pre

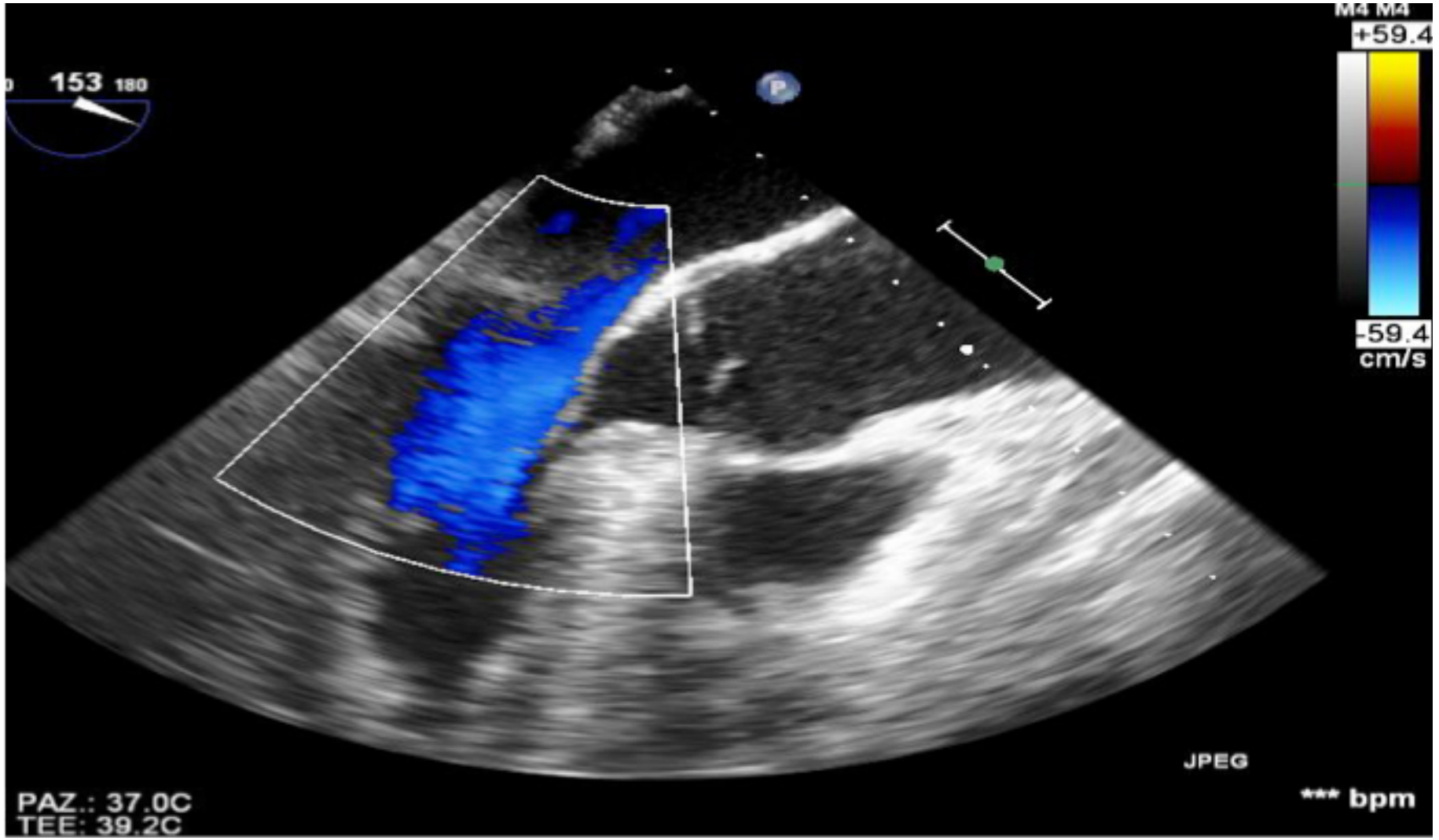
Courtesy Dr. S.Salizzoni and Prof.M.Rinaldi, Univ. of Torino, Italy

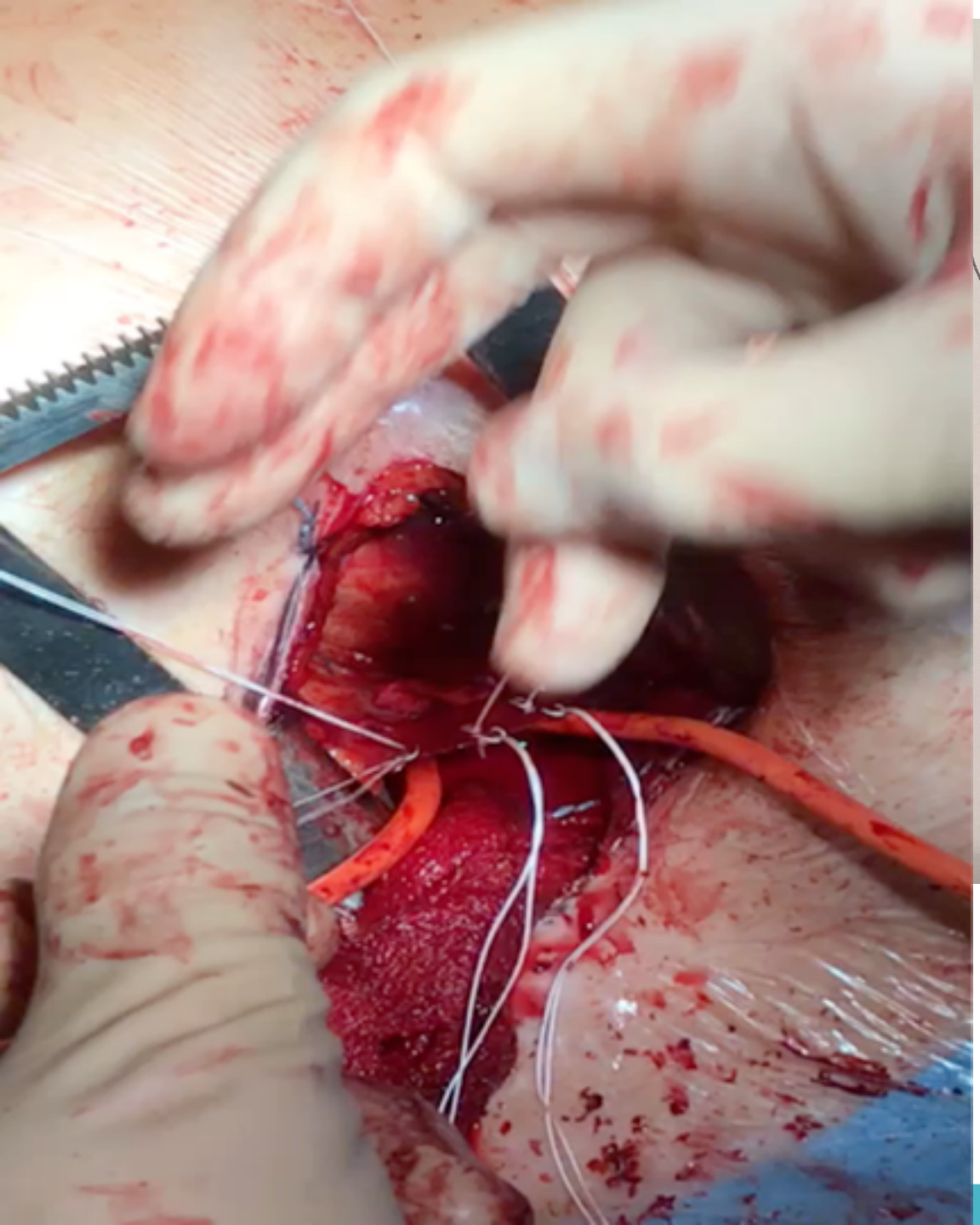


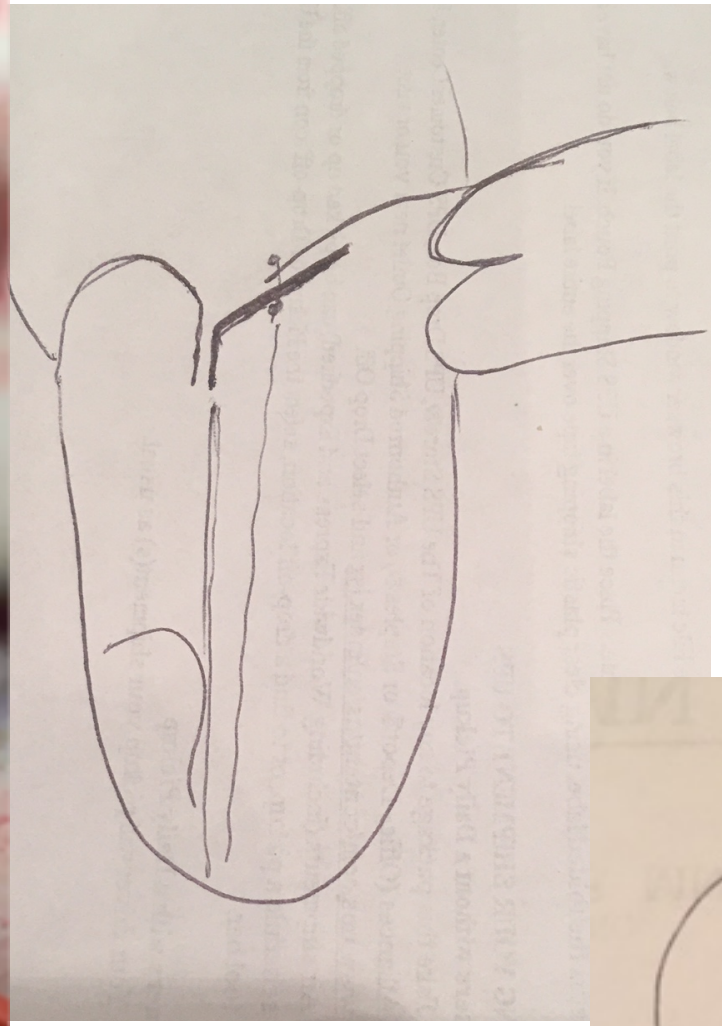




NeoChords to treat SAM: post

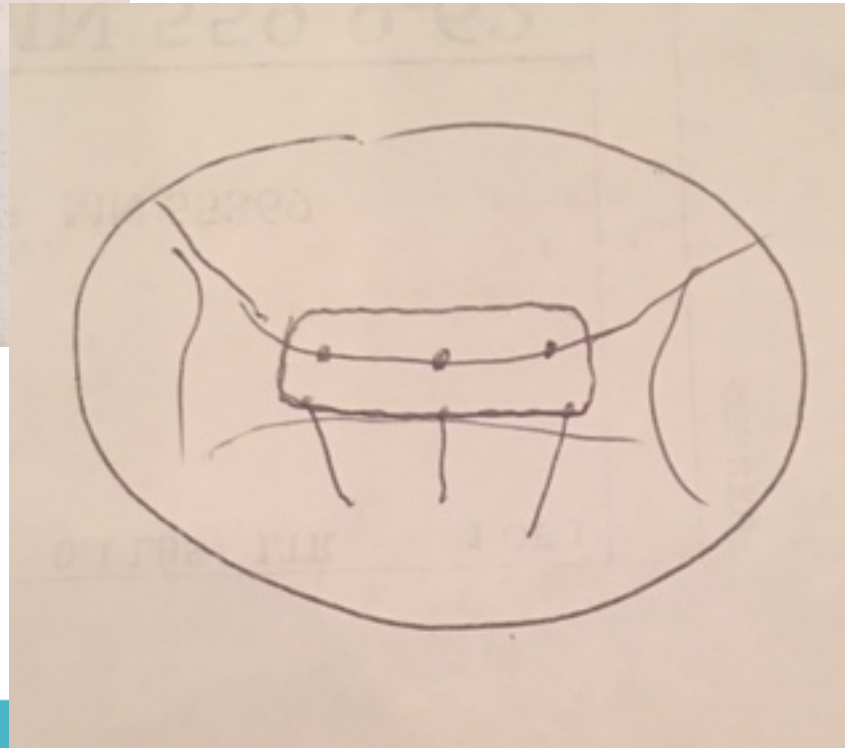






ANTERIOR LEAFLET AUGMENTATION

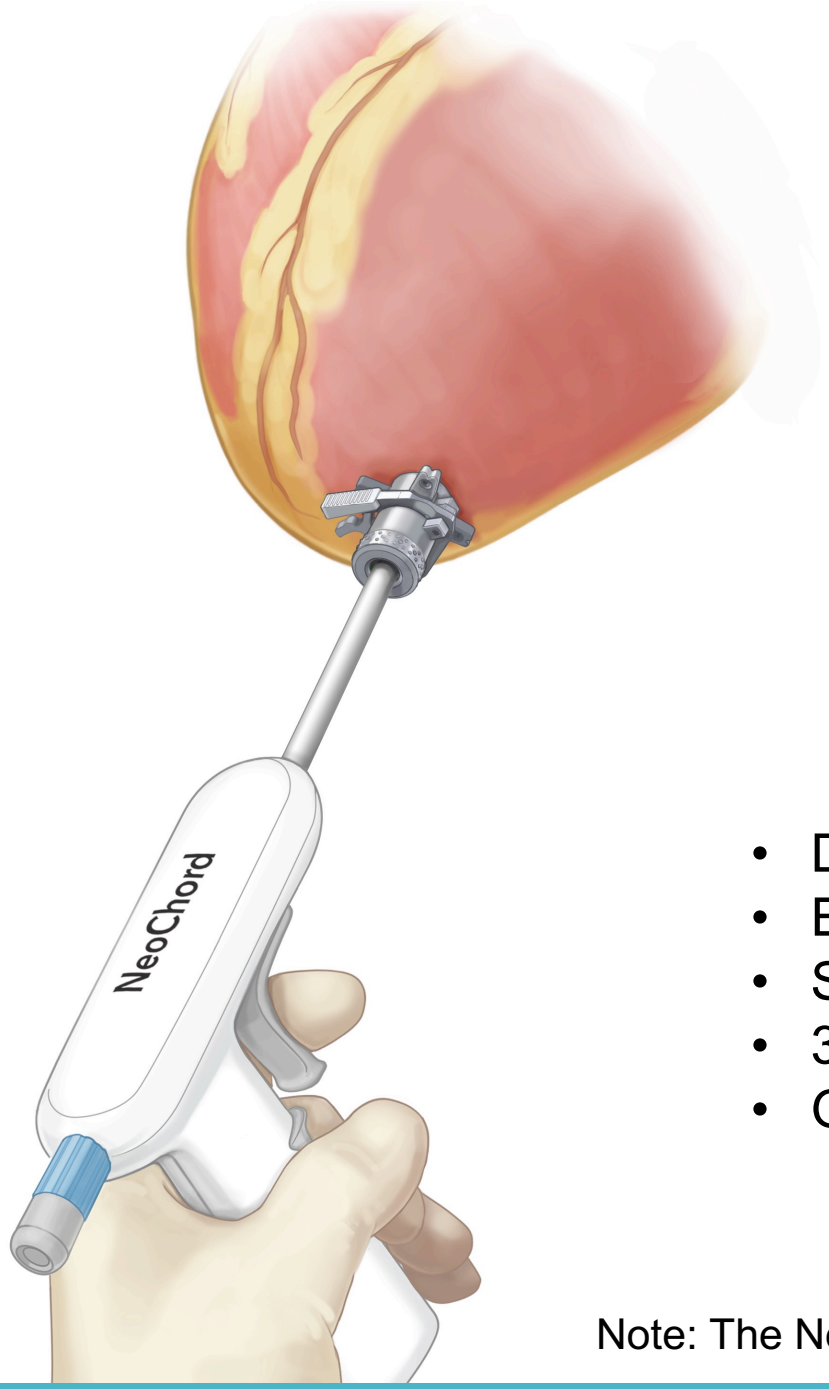
Courtesy Prof. M.Rinaldi
Dr. S.Salizzoni
University of Turin, Italy

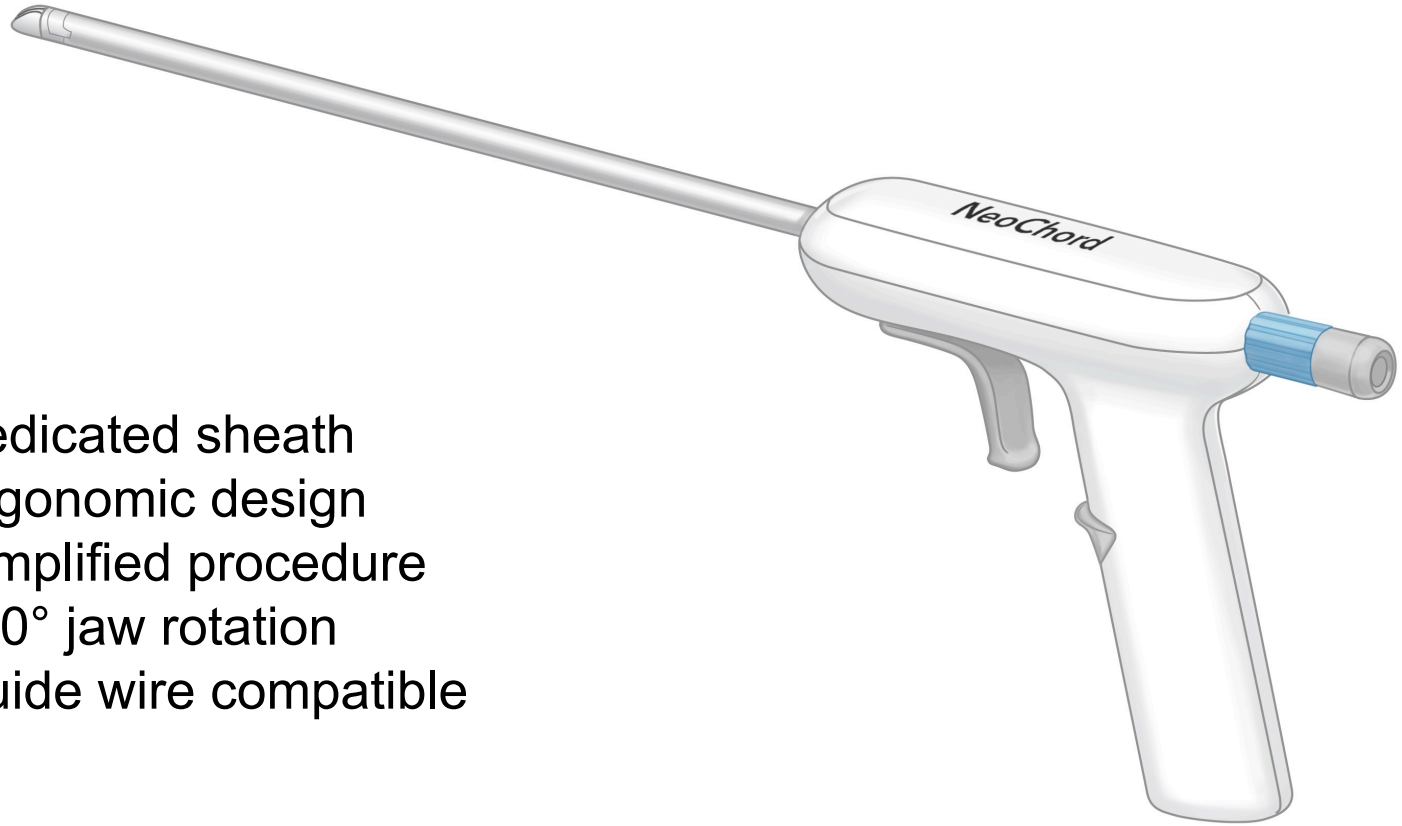


In conclusion: why do I go for NeoChord?

- Largest worldwide experience and follow-up
- Good durability of results
- chordae are placed on the leaflet edge, where the native broken chordae insert
- Can treat anterior and posterior leaflet prolapse and flail, SAM and can also be used for leaflet augmentation

NeoChord Generation 2

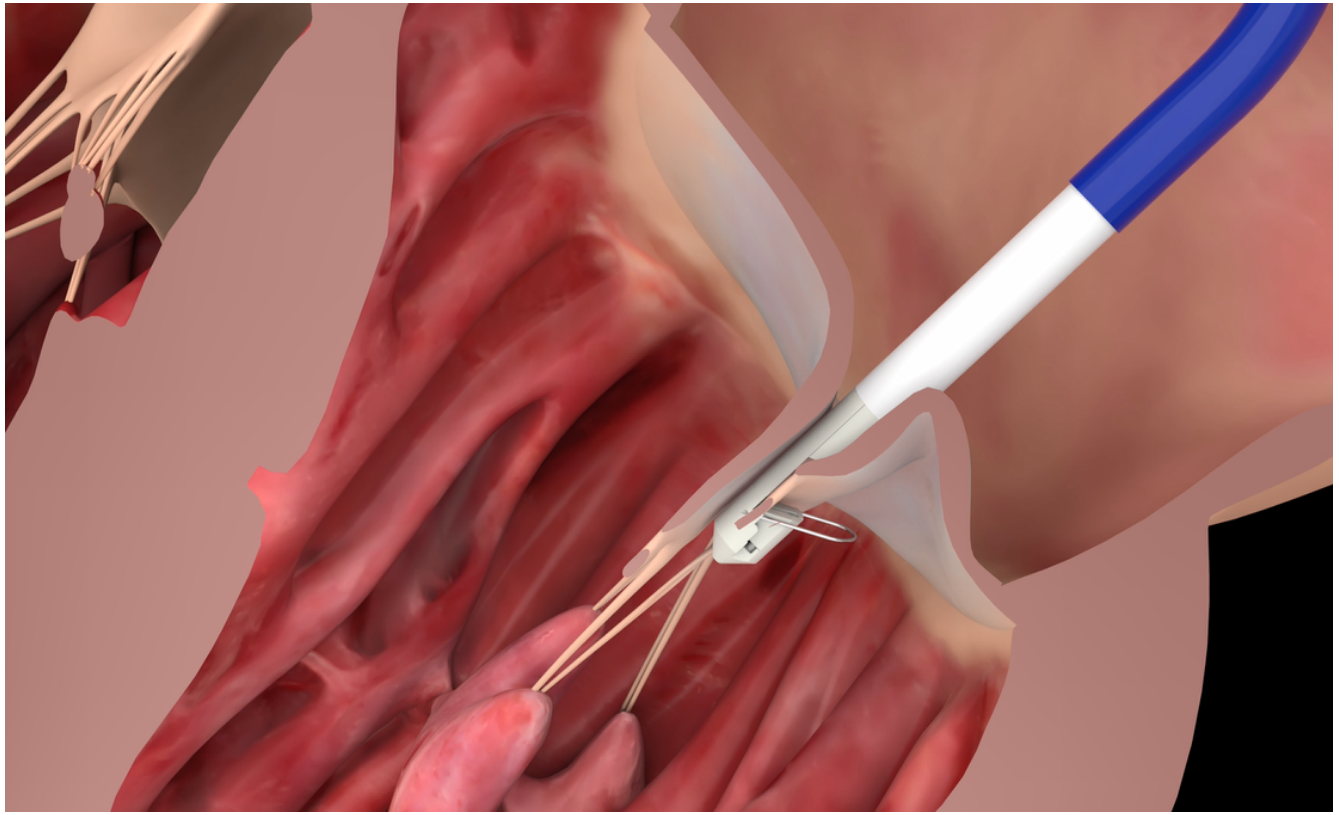




- Dedicated sheath
- Ergonomic design
- Simplified procedure
- 360° jaw rotation
- Guide wire compatible

Note: The NeoChord Gen 2 is a future device that is not approved in any market.

NeoChord Transcatheter / Transseptal



Procedure replicates current approach:

Leaflet capture

Needle actuation

Girth hitch knot

Separate anchoring system in LV

Tensioning and release

Note: This is a future device that is not approved in any market.

THANK YOU