

# Transcatheter closure of post-surgical paravalvular leaks

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**Research, Digital and Innovation Committee EAPCI**

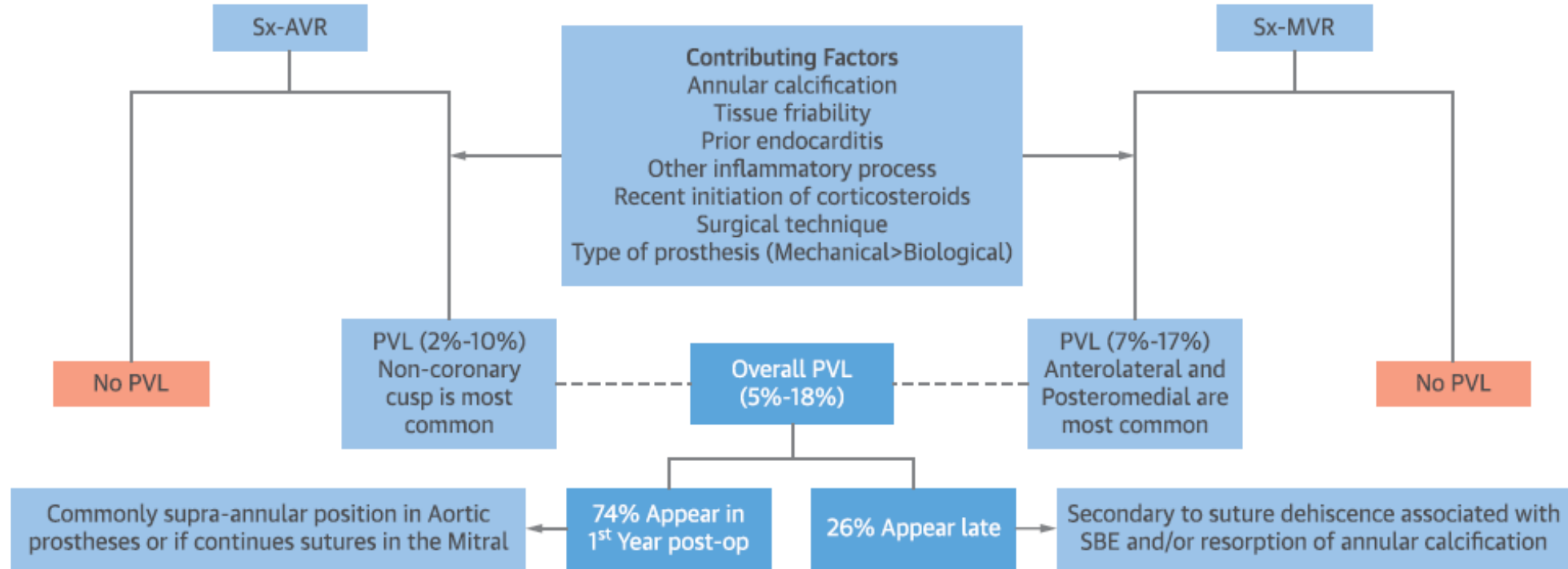
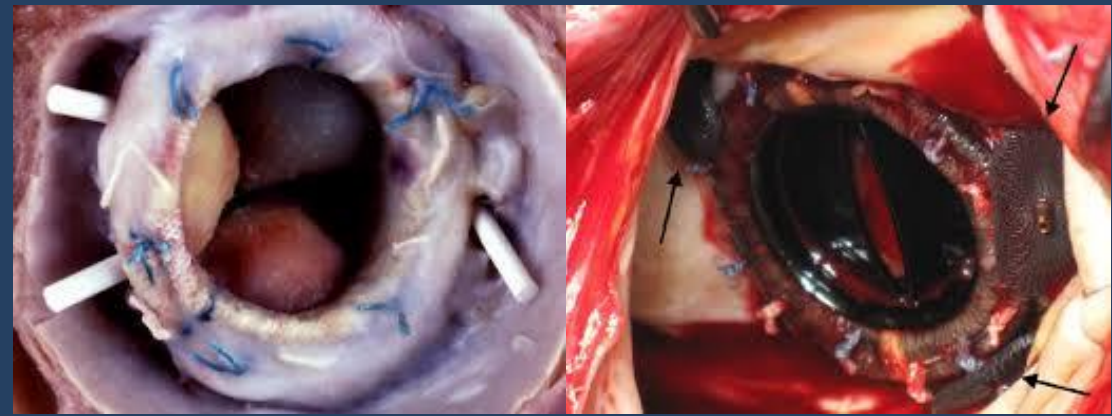


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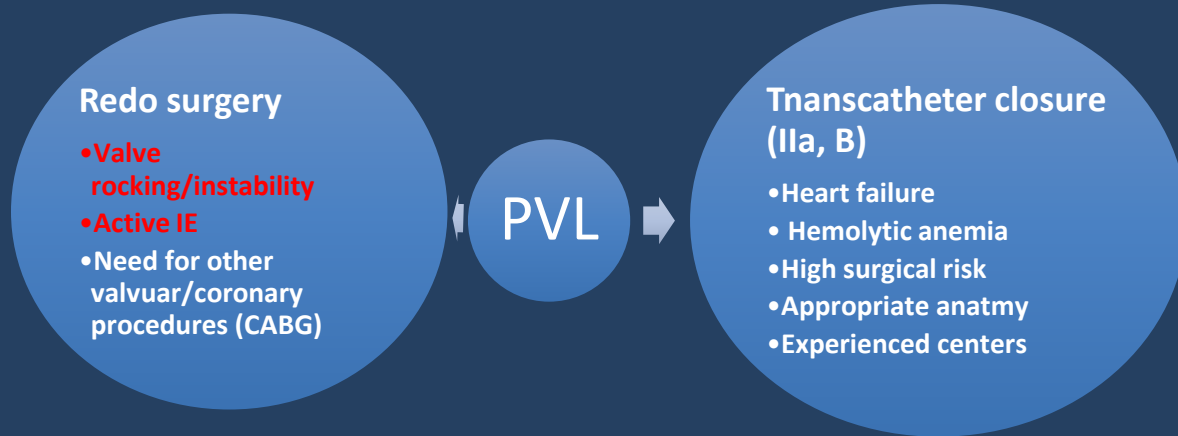
# Disclosure Statement of Financial Interest

I, Wojciech Wojakowski: DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

# Transcatheter paravalvular leak closure



# Transcatheter paravalvular leak closure



2a	B-NR	3. In patients with prosthetic paravalvular regurgitation with the following: 1) either intractable hemolysis or NYHA class III or IV symptoms and 2) who are at high or prohibitive surgical risk and 3) have anatomic features suitable for catheter-based therapy, percutaneous repair of paravalvular leak is reasonable when performed at a Comprehensive Valve Center (5-9).
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ACC/AHA 2020

Transcatheter closure should be considered for suitable paravalvular leaks with clinically significant regurgitation and/or haemolysis in patients at high or prohibitive surgical risk. <sup>547</sup>	IIa	B
Decision on transcatheter or surgical closure of clinically significant paravalvular leaks should be considered based on patient risk status, leak morphology, and local expertise.	IIa	C

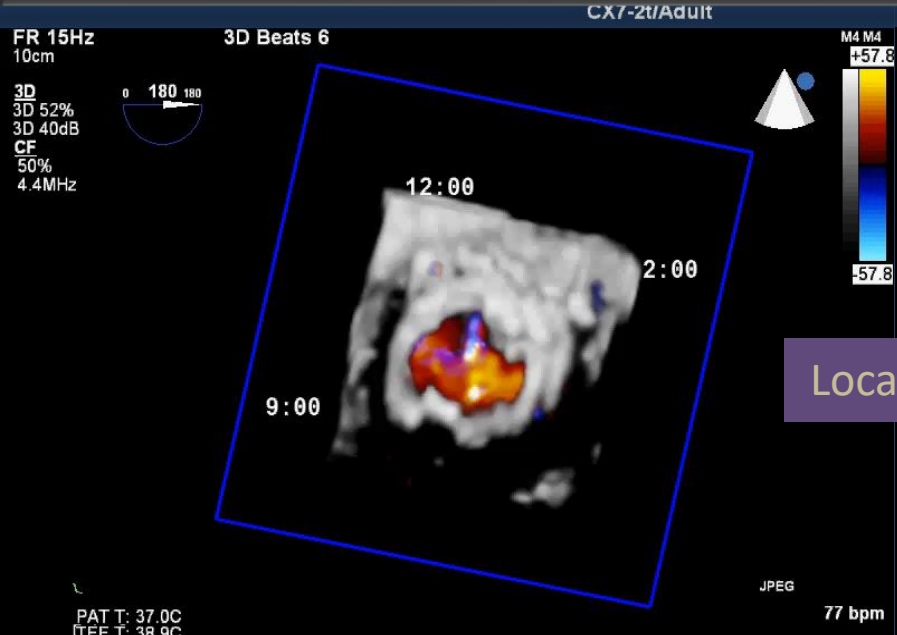
ESC/EACTS 2021

- **HF symptoms (NYHA II-IV class) despite optimal pharmacotherapy and/or hemolysis**
  - **≥ 2+ PVL jet in color Doppler mapping plus at least one of the following:**

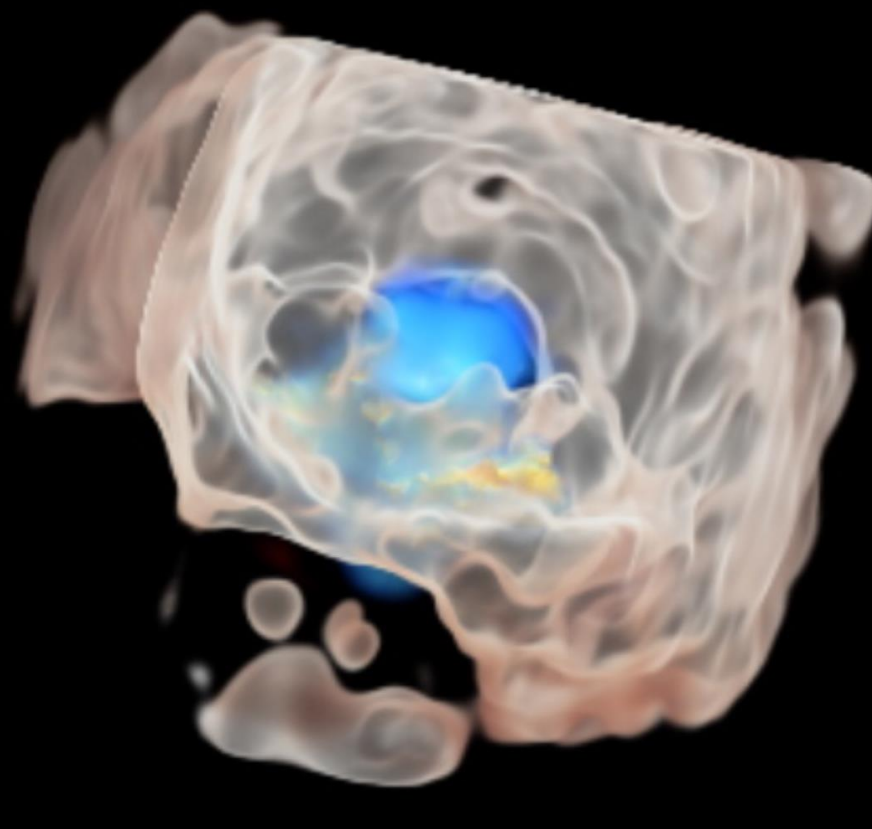
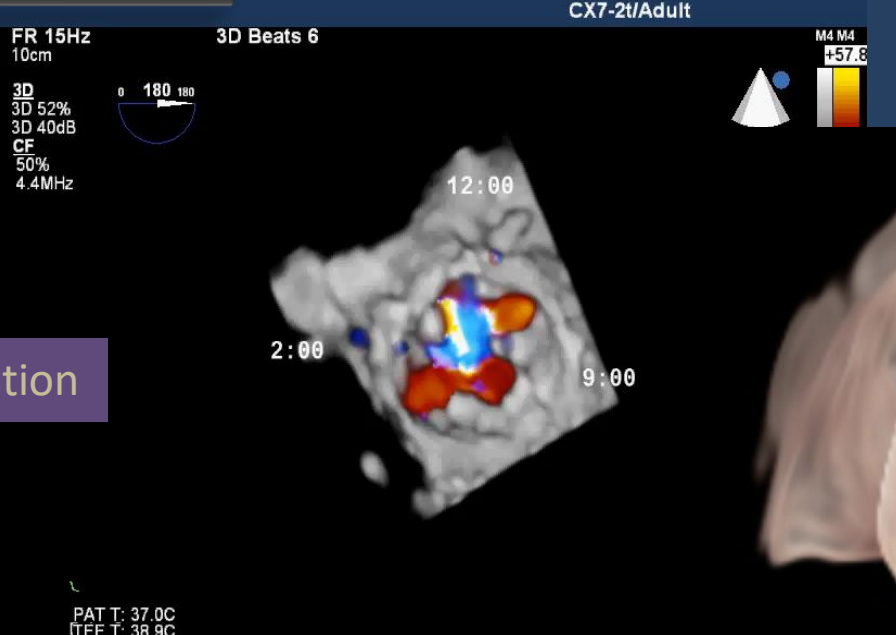
- Mitral PVL:**
- systolic flow reversal in at least one PV
  - increased calculated PAP
  - lack of left atrium (LA) size reduction after MVR or recurrent and progressive LA dilation
  - forward transprosthetic flow velocity higher than expected with given prosthesis type and size, provided normal function of prosthetic leaflets

- Aortic PVL:**
- holodiastolic flow reversal in the proximal part of descending aorta
  - lack of left ventricle (LV) size reduction after aortic valve replacement (AVR)
  - recurrent and progressive LV dilation in postoperative course
  - forward transprosthetic flow velocity higher than expected with given prosthesis type and size, provided normal function of prosthetic leaflets

# Diagnosis



Location



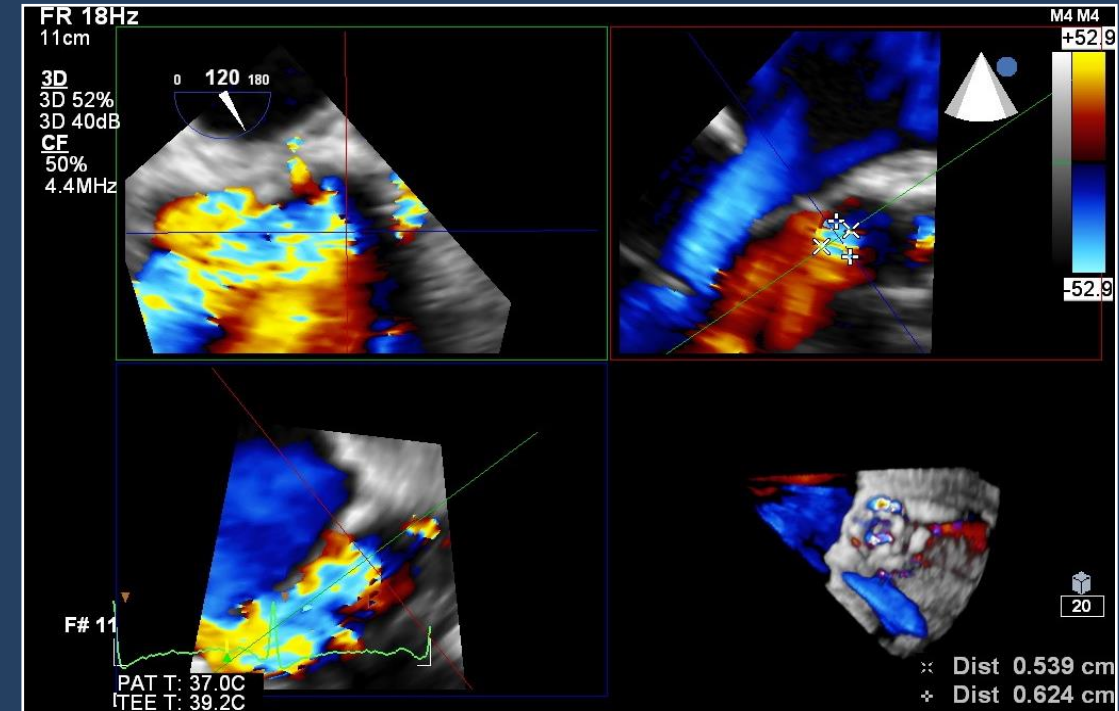
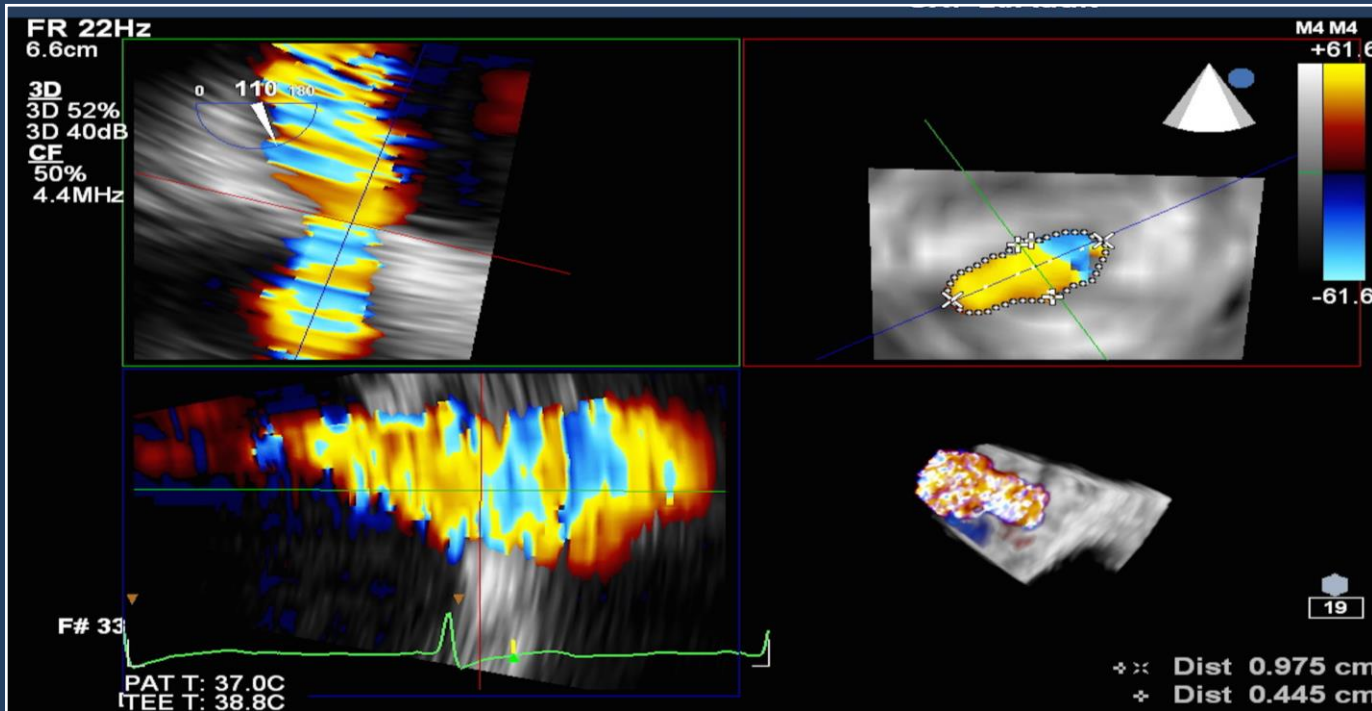
Sutures  
Stability  
Thrombus



## MV

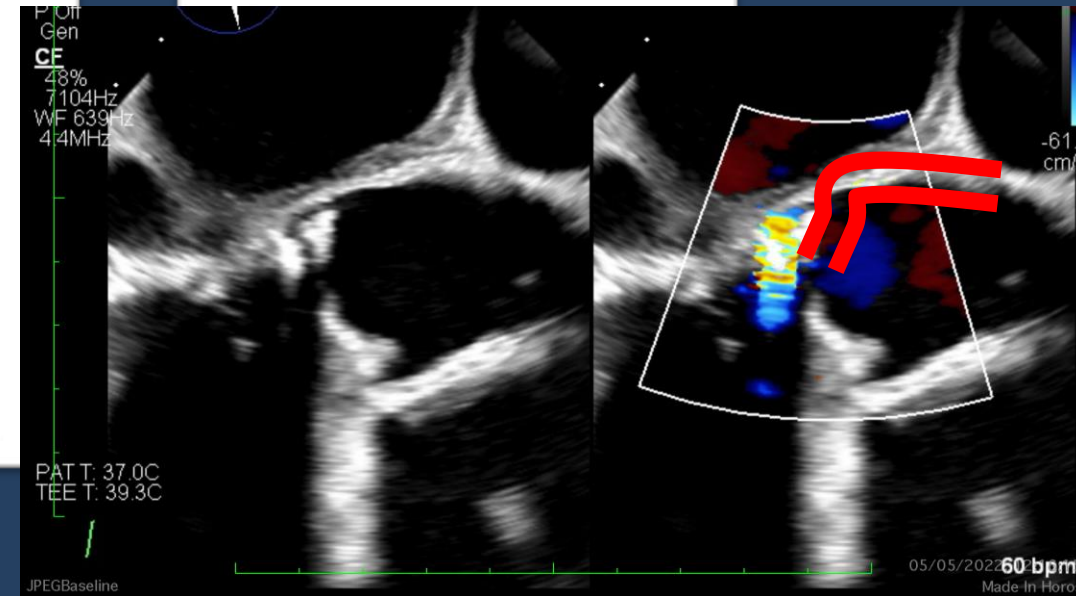
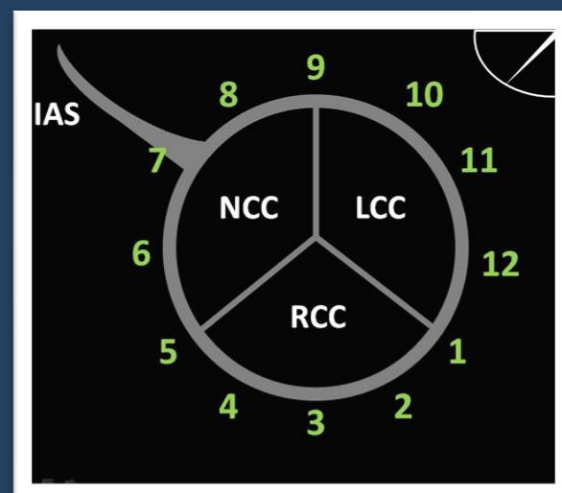
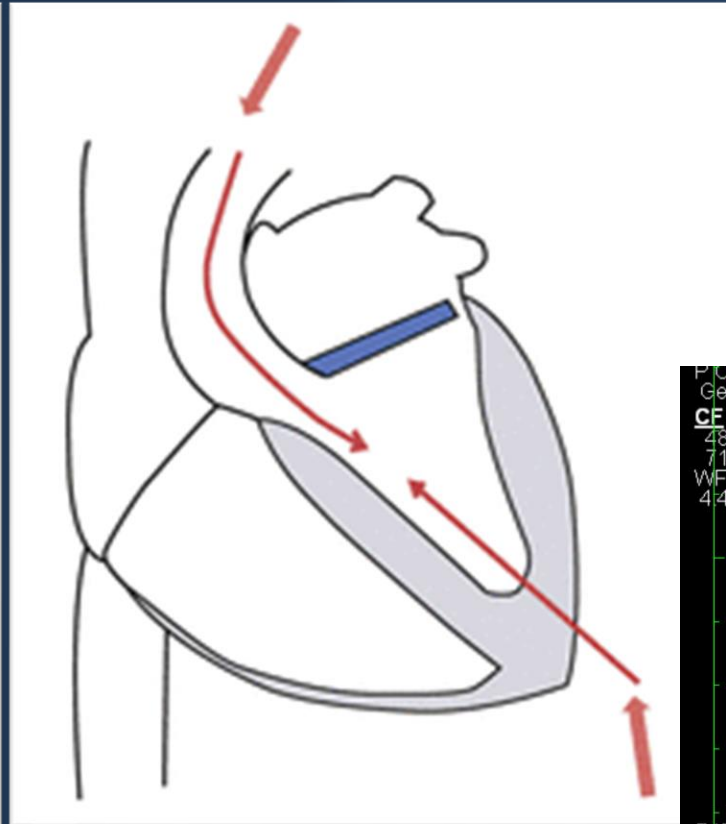
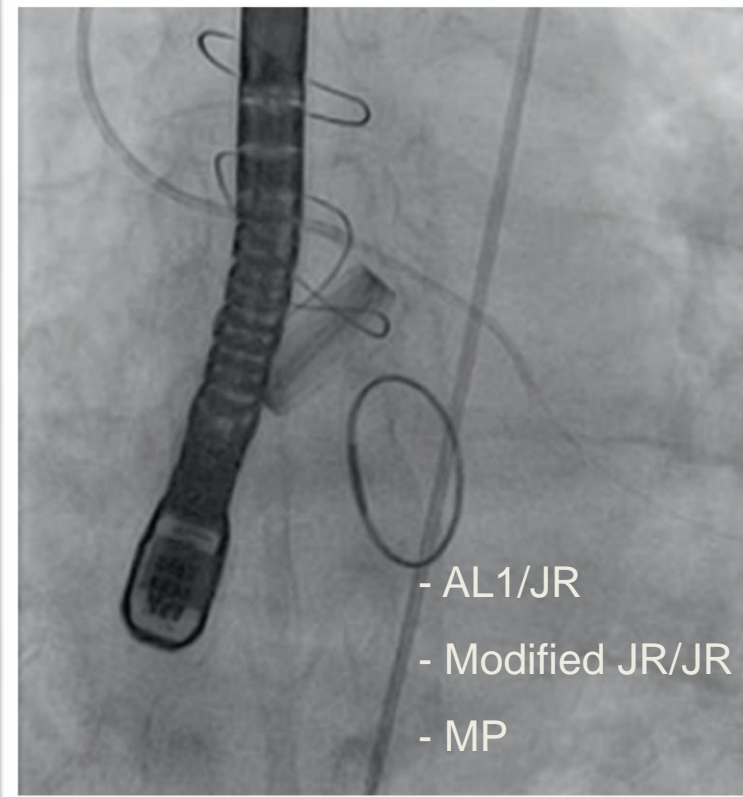
## CSA in 3D TEE MPR

## AV



Technique	Benefit
Zoom mode + CD acquisition of small volume of tissue containing PVL channel only	Highest possible volume rate
Single-beat acquisition only	Avoidance of stitching artifacts
Multiplanar presentation	Measurements of CSA of VC, minimum and maximum dimensions of VC, channel length

# Aortic PVL



- Mother-and-a-child technique
- 6 F coronary guide catheter and 125 cm 5F coronary diagnostic catheter
- Delivery sheath (5-9F) over stiff wire
- Shadowing from prosthetic valve/3D not very useful

# Hybrid imaging

Demo System Help PHILIPS

Echo X-Ray

Select Layout ?

Select View ?

C-arm Free Echo X-Ray

Annotation ?

Clear All

✓	Name	Color
✓	Marker 1	●

✓ Show Names

CAUD 52°  
RAO 153°

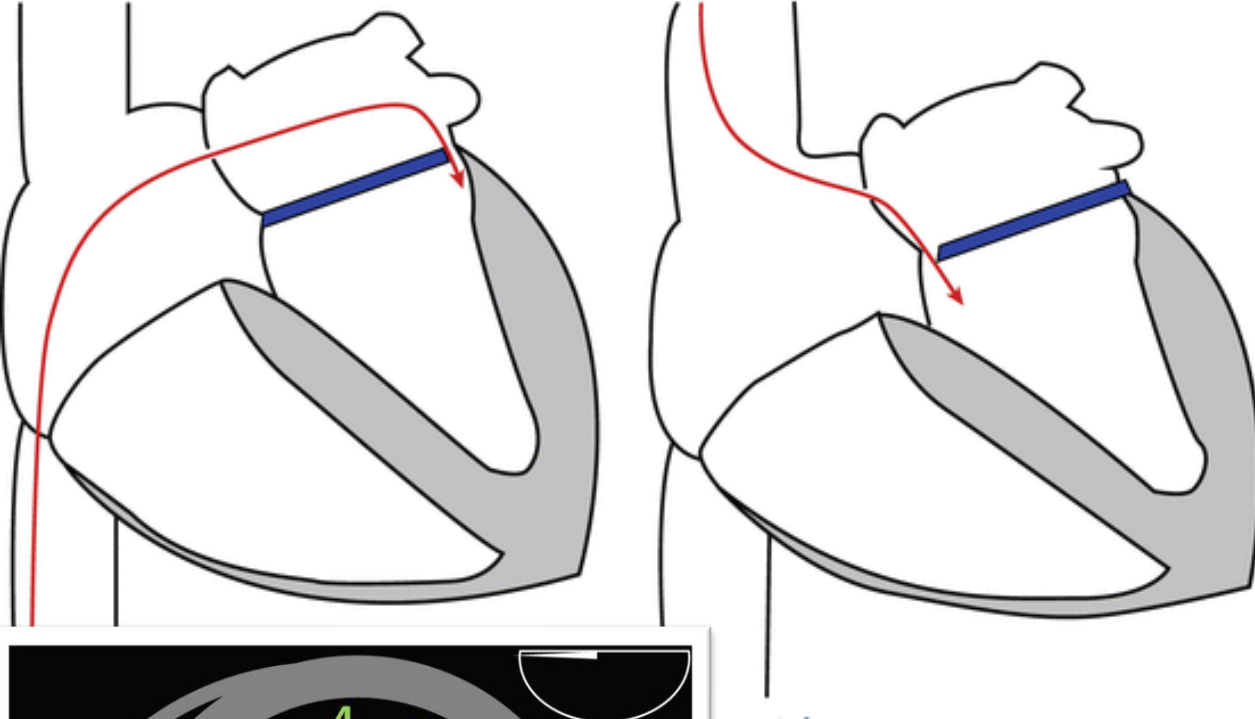
CRAN 5°  
LAO 35°

The image displays a hybrid imaging software interface. On the left is a control panel with sections for 'Select Layout' (showing icons for C-arm, Free, Echo, and X-Ray), 'Select View' (with a 142-degree angle indicator), 'Annotation' (with a 'Marker 1' entry), and 'Show Names' (checked). The main area is split into two panels: 'Echo' (ultrasound) and 'X-Ray' (fluoroscopic). Both panels show a 'Marker 1' with a yellow circle. The X-Ray panel features a pink polygonal annotation around a surgical instrument. At the bottom, a small inset shows a green 3D model of the instrument. The bottom right corner displays patient orientation angles: CAUD 52°, RAO 153°, CRAN 5°, and LAO 35°. The PHILIPS logo and menu items (Demo, System, Help) are at the top right.

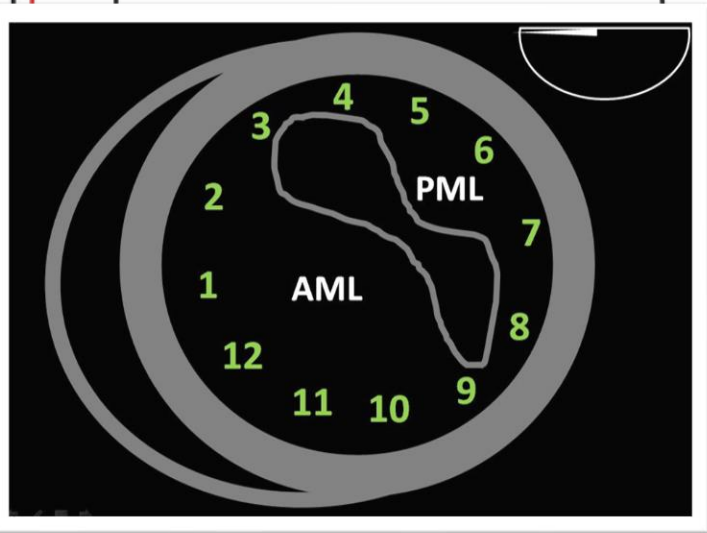
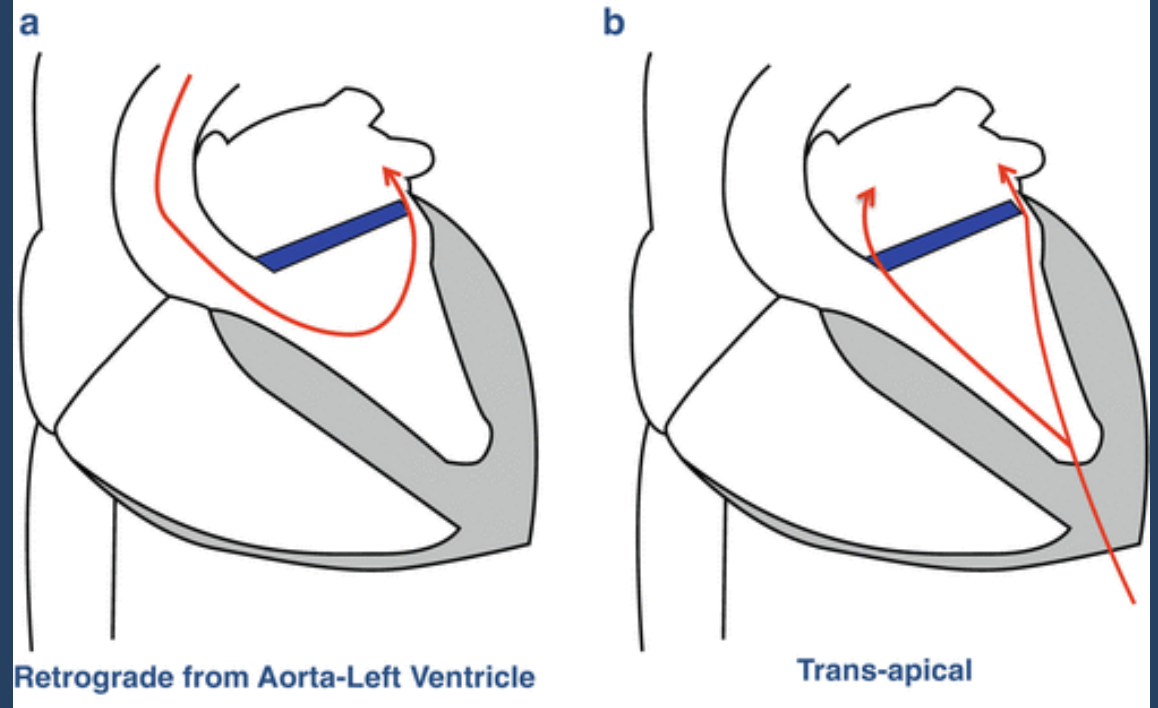


# Mitral PVL

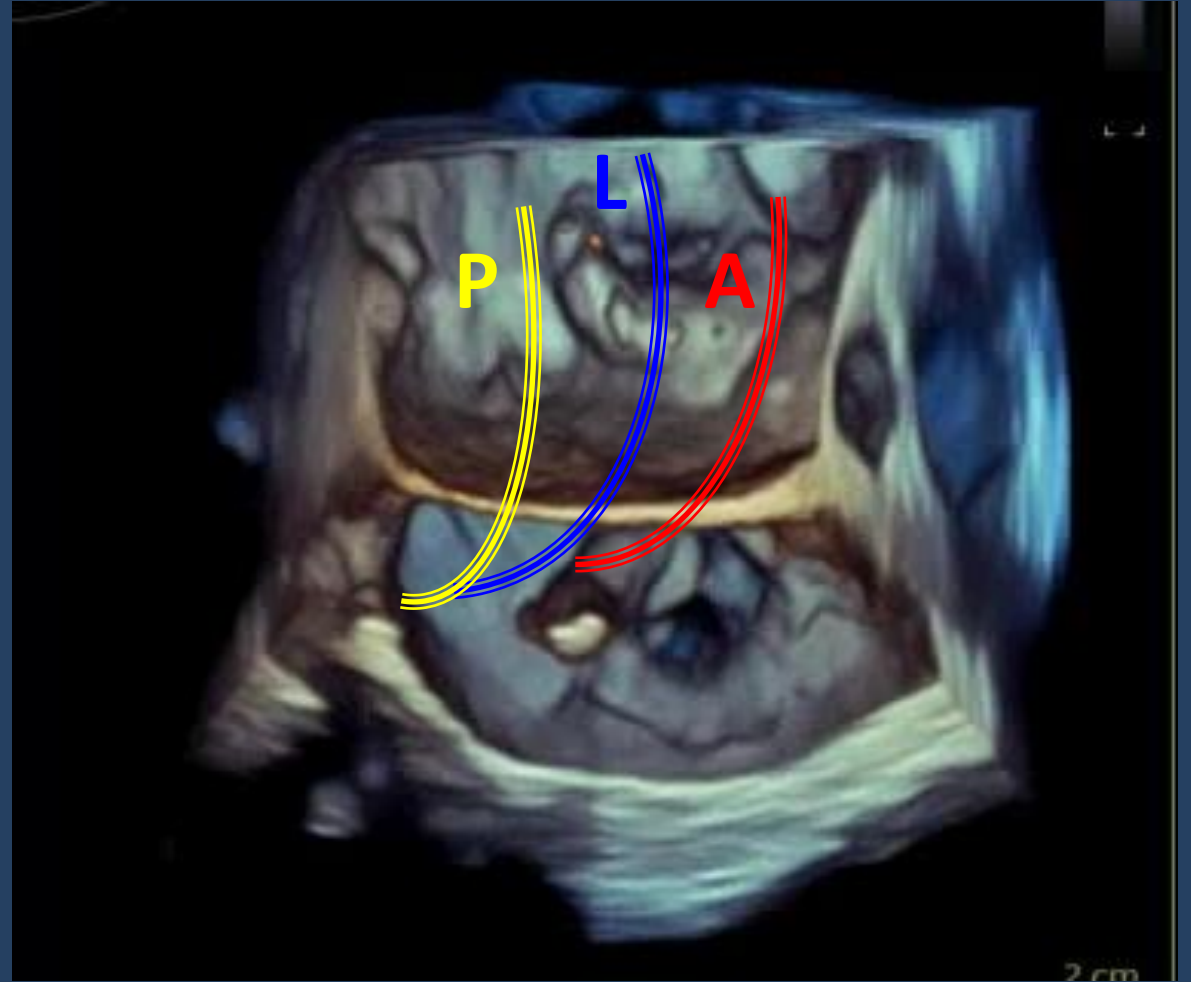
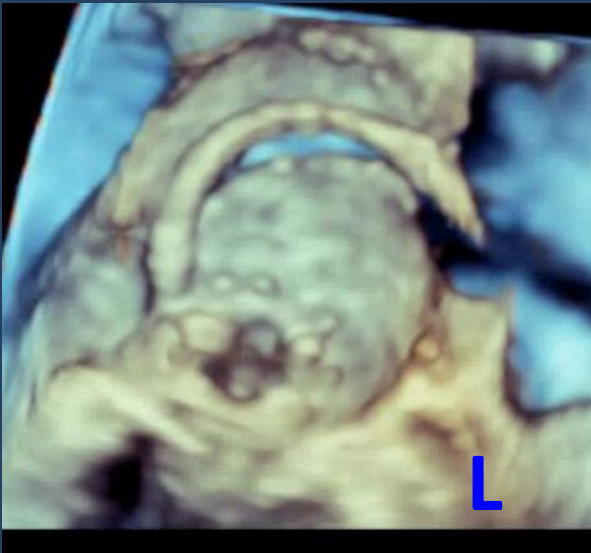
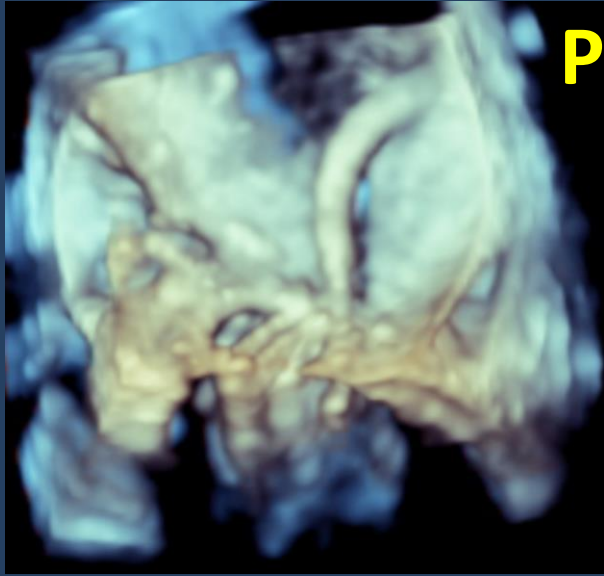
Mitral PVLs : anterograde approaches



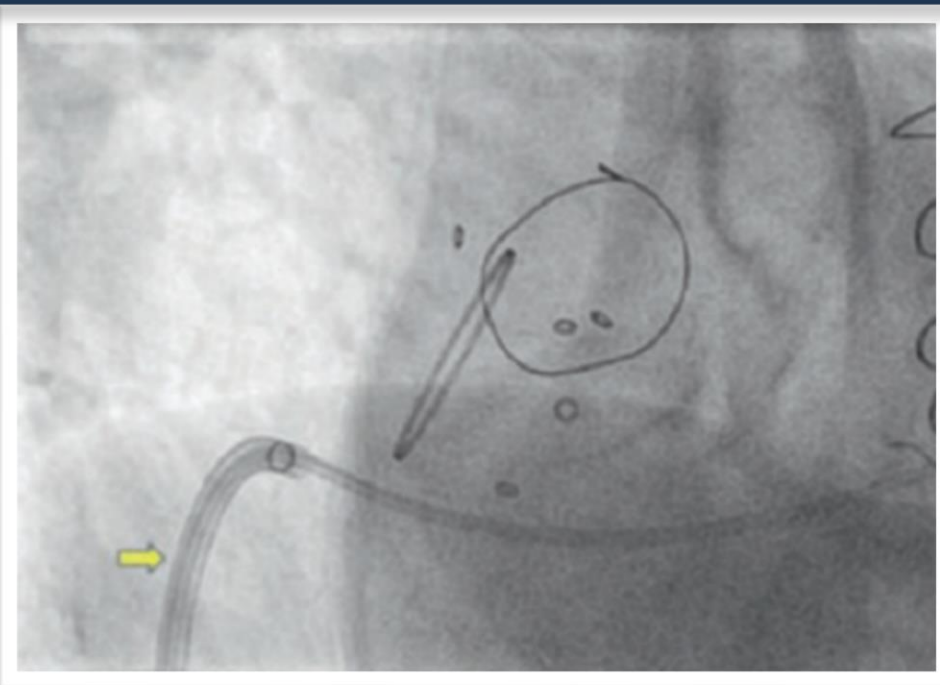
Mitral PVLs : retrograde approaches



# IVS Puncture



# COMBO technique for Mitral PVL



**Extending Your Reach**

The range of Occlutech's steerable sheaths is used to deliver LAA occluders, position ablation catheters or helping and directing in procedures where it improves the maneuverability and placement.

Occlutech's steerable sheaths are designed to offer a soft flexible tip, reducing the risk of atrial wall damage or perforation when navigating the cardiac atria.

The thin braided wall technology allows an optimal relation between excellent steerability and kink resistance while maintaining an optimal relationship between internal and external diameters.

**Steerability**

The responsive curve allocation allows for an optimal steerability. The braided catheter ensures curve durability throughout the procedure.

**Deflection**

The bidirectional deflection technology allows up to 180 degrees of deflection while maintaining a relatively small curl allowing tight navigation.

**Profile**

The low crossing profile provides a smooth transition from the dilator to the sheath introducer reducing the trauma and damage to the atrial septum.

**Features and benefits**

- Radiopaque marker band allowing optimal placement
- Atraumatic tip
- Reliable haemostatic valve reducing bleeding
- Braided construction avoiding kinking
- Side port with 3-way stop-cock
- Lubricious coating
- Smooth transition giving low crossing profile
- Ergonomics easy to use handle giving precise steering control
- Compatible with a wide range of catheters and implants

**Handling**

The ergonomically designed handle makes the handling of the sheath easy and comfortable. The optimized grip allows for greater control during the procedure.

**Dedication to Innovation**

Occlutech is constantly striving to improve its product offering for all indications in the field of structural heart disease. With the OSGS we have created a conduit that allows the perfect positioning and delivery of a large range of interventional devices and interventional catheters.

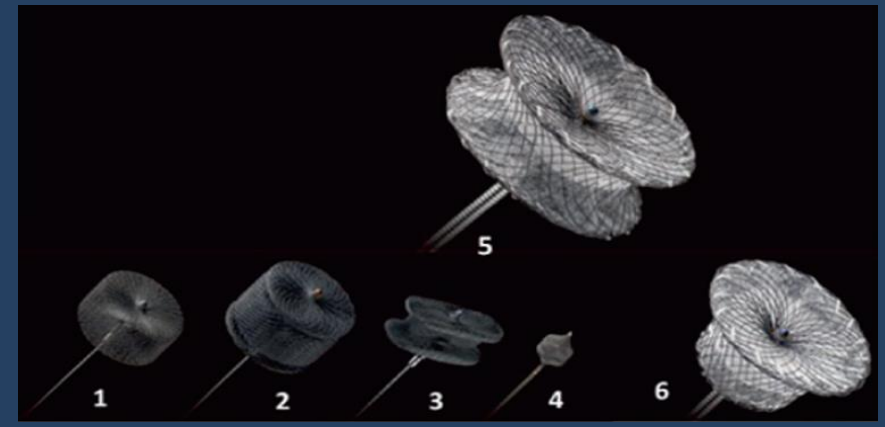
**Perfecting Performance**

Occlutech® Steerable Guiding Sheath

- Steerable sheath (8.5 Agilis; 12F Flexcath; 14F Occlutech)
- 6 F coronary guide catheter and 125 cm 5F coronary diagnostic catheter
- Delivery sheath (5-9F) over stiff wire or up to 3 coronary catheters
- Wire in the left atrium to provide distance of the tip

# Current device selection

Vascular plugs (AVPII, AVPIII, AVPIV) and PDA occluders (Abbott)  
(AVP III – approved for PVL)



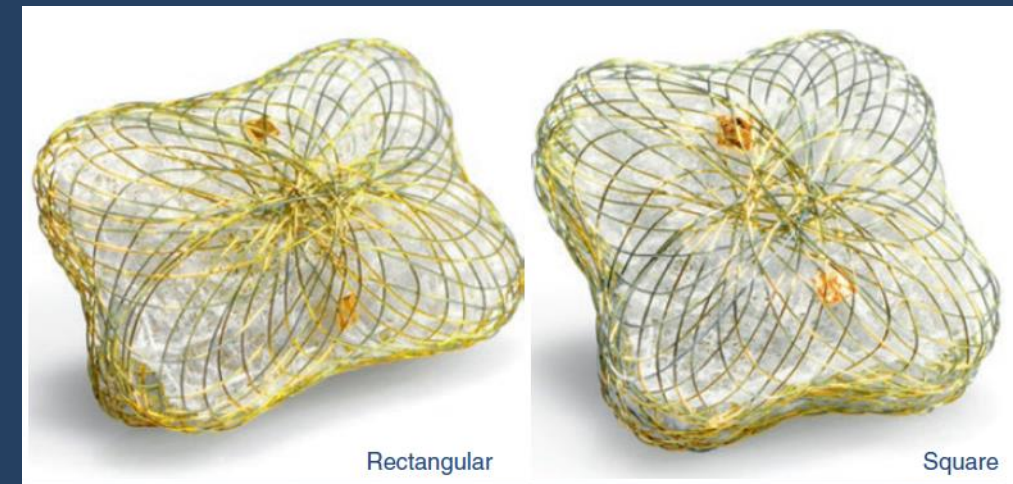
Sealing material



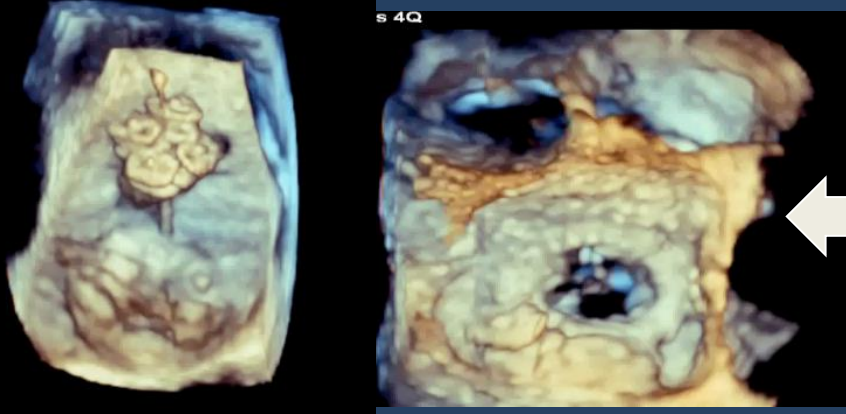
Controlled orientation



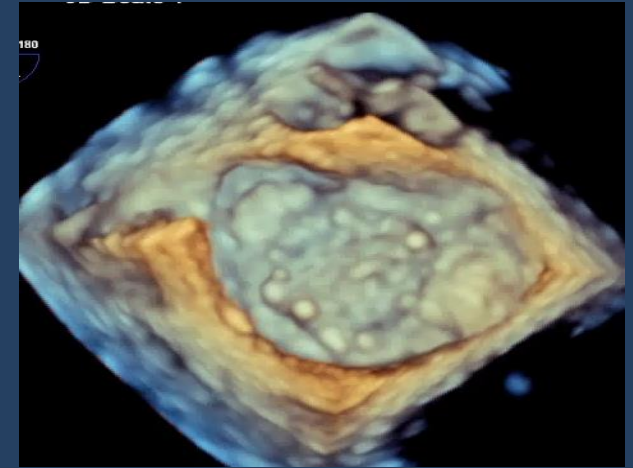
PLD device (Occlutech) (CE-Marked for PVL)



# Current device selection



oversize

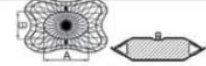


Delivery	Sizes [mm]
4F	4x2, 6x3
5F	8x4, 10x3
6F	10x5
7F	12x3, 12x5, 14x3, 14x5



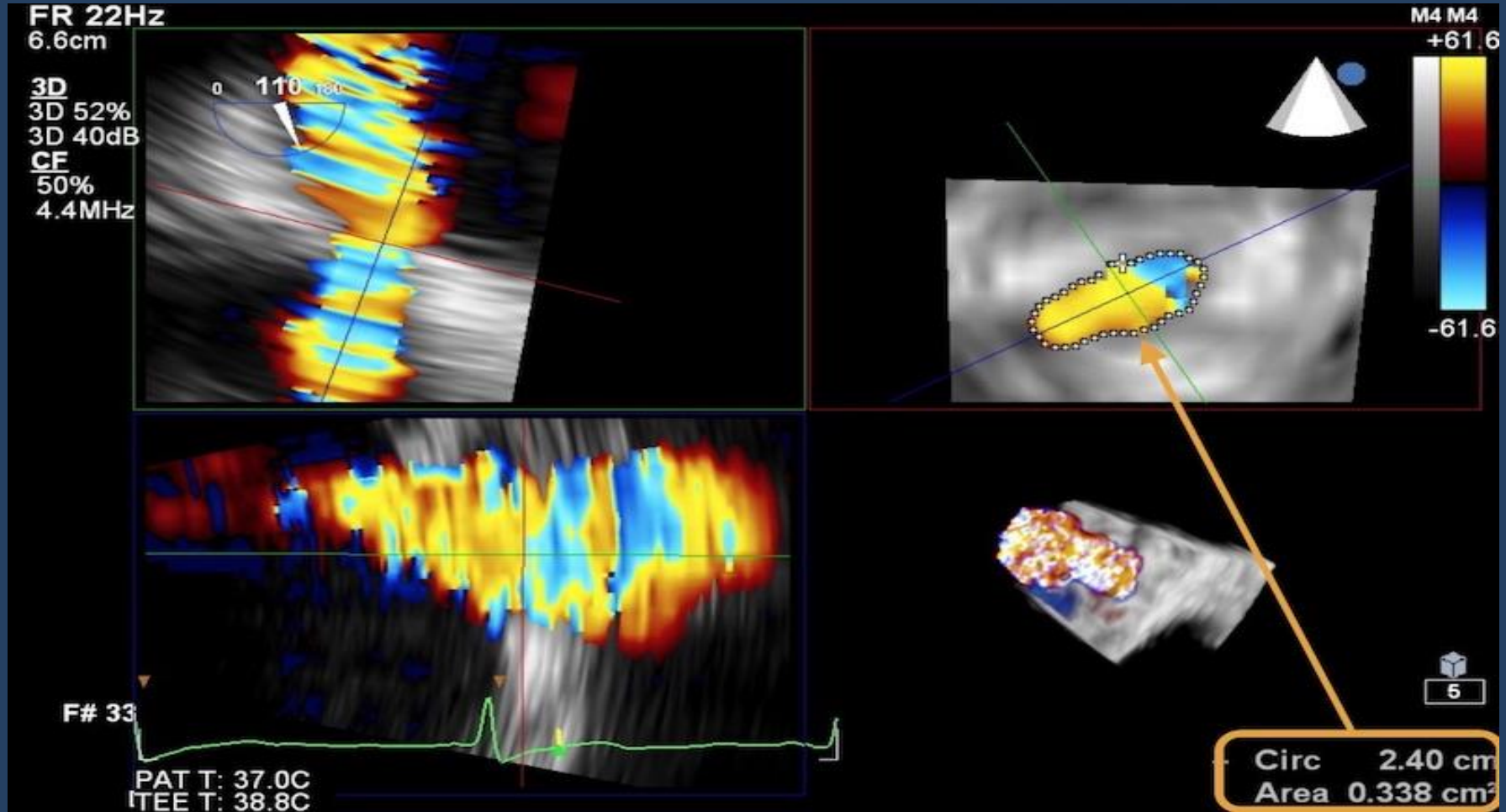
Cover all anatomies  
(long, crescent)



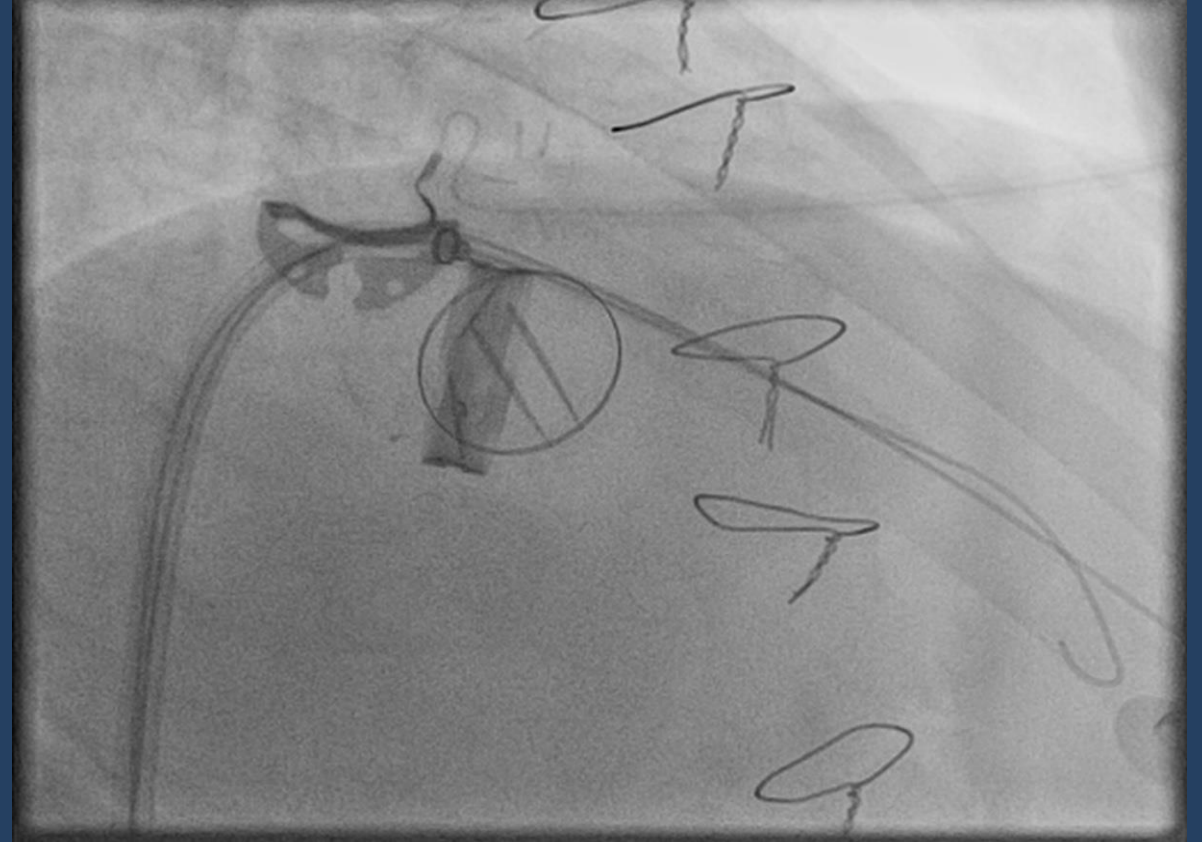
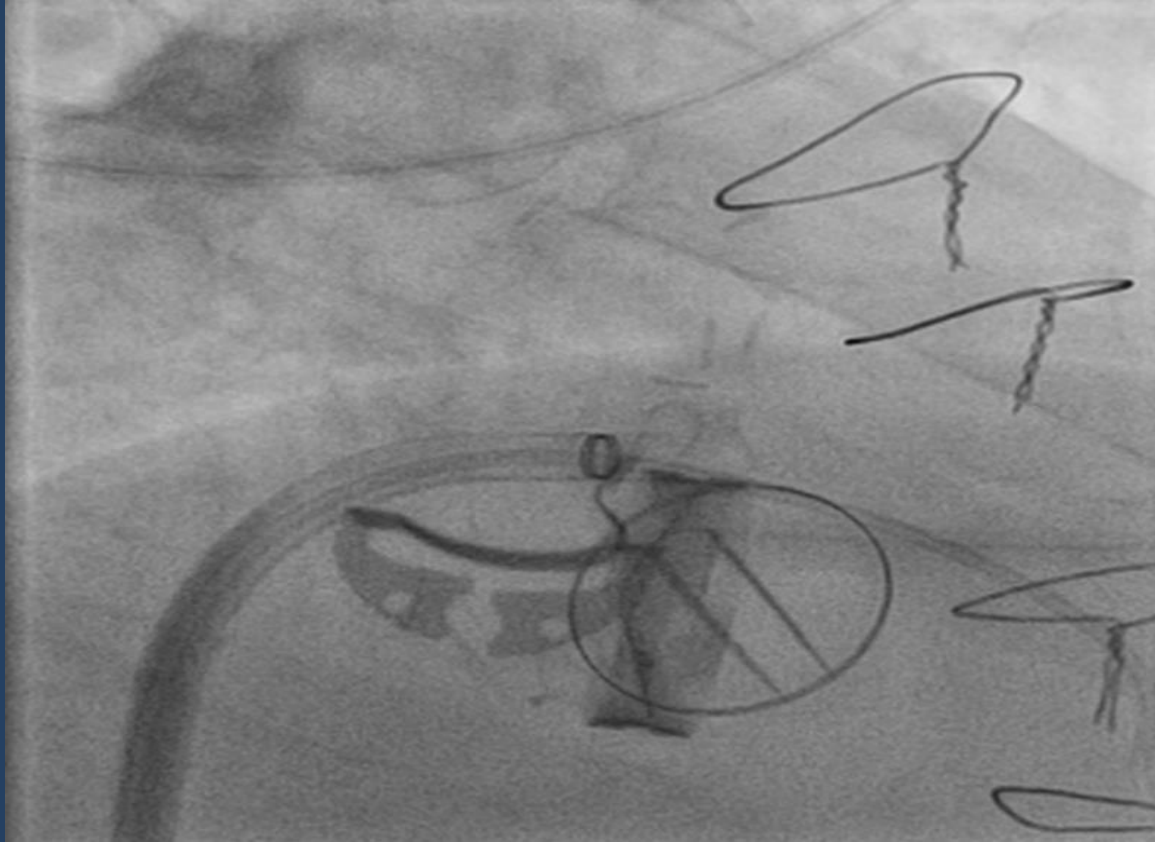
Occlutech <sup>®</sup> PLD RECTANGULAR_W*						
REF NO	D1 [mm]	D2 [mm]	Ax B [mm]	Introducing system **		Flex Pusher Item no.
				ID [mm]	Size [F]	
61 PLD 04W	11.5	10	4x2	2.21	6	50FP100L Dark Blue
61 PLD 06W	14	12.5	6x3	2.21	6	50FP100L Dark Blue
61 PLD 08W	16.5	15	8x4	2.54	7	50FP100L Dark Blue
61 PLD 10W	19	17	10x4	2.87	8	50FP100L Dark Blue
61 PLD 12W	21	19	12x5	3.20	9	50FP120L Dark Green
61 PLD 14W	24	22	14x6	3.20	9	50FP120L Dark Green
61 PLD 16W	26.5	24.5	16x8	3.40	10	50FP120L Dark Green
61 PLD 18W	28.5	26.5	18x10	3.40	10	50FP120L Dark Green

Suitable for multiplug AVP III	Suitable for single PLD
Irregular/crescent CSA of VC	Round /oval CSA of VC
Channel length >5 mm	Channel length ≤5 mm
Bulks of calcium within channel or surrounding structures that might impede full expansion of discs	No structures potentially impeding disc apposition

# Case example

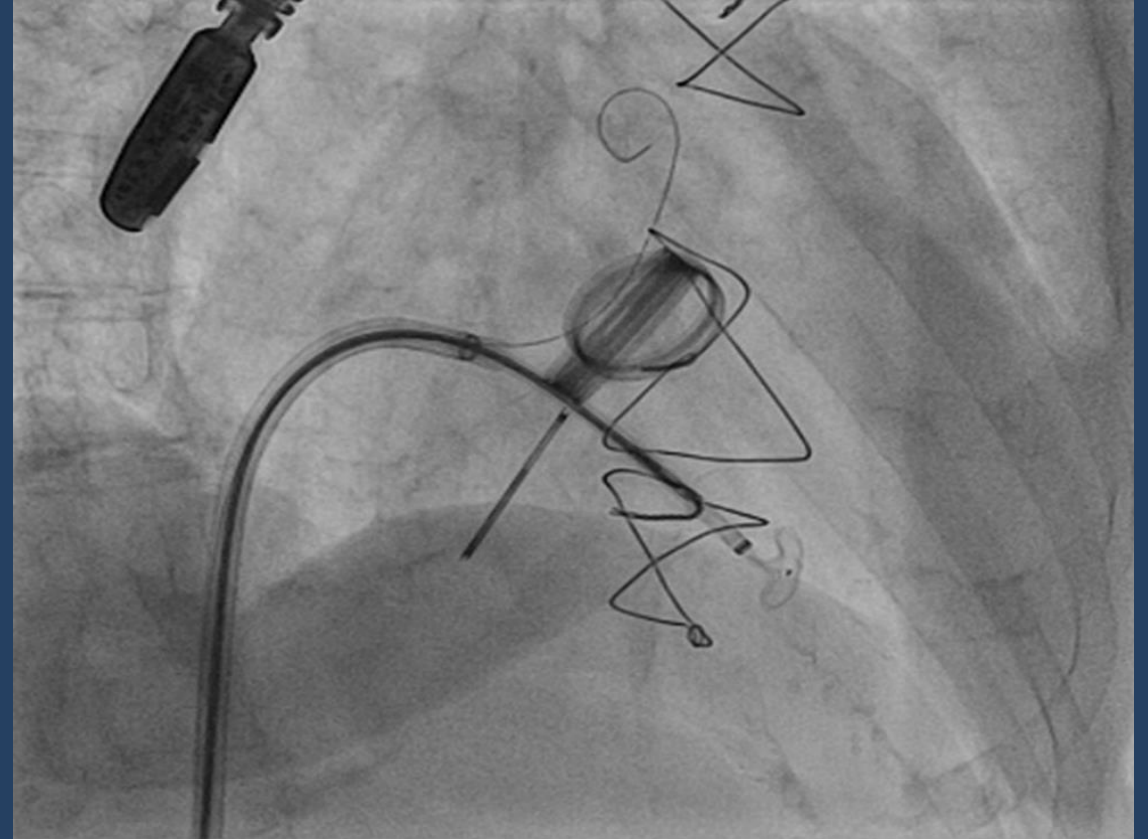
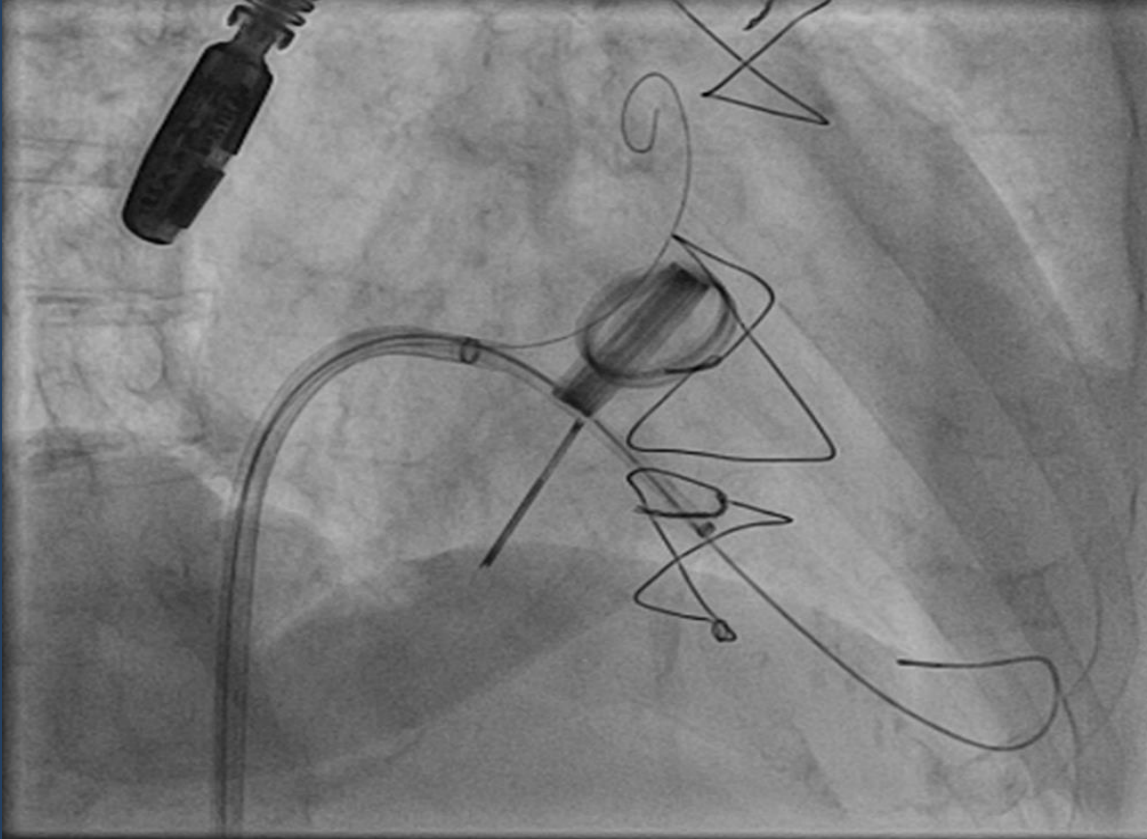


# Case example



PVL crossing

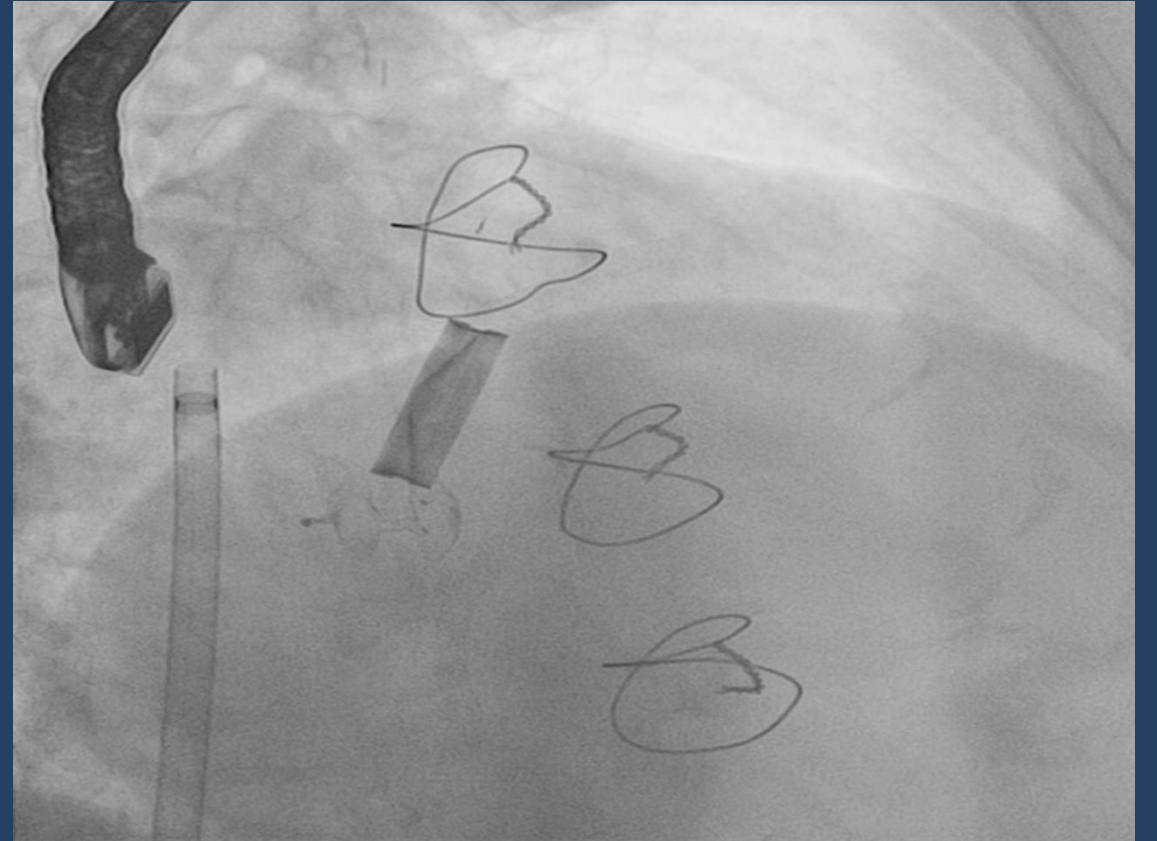
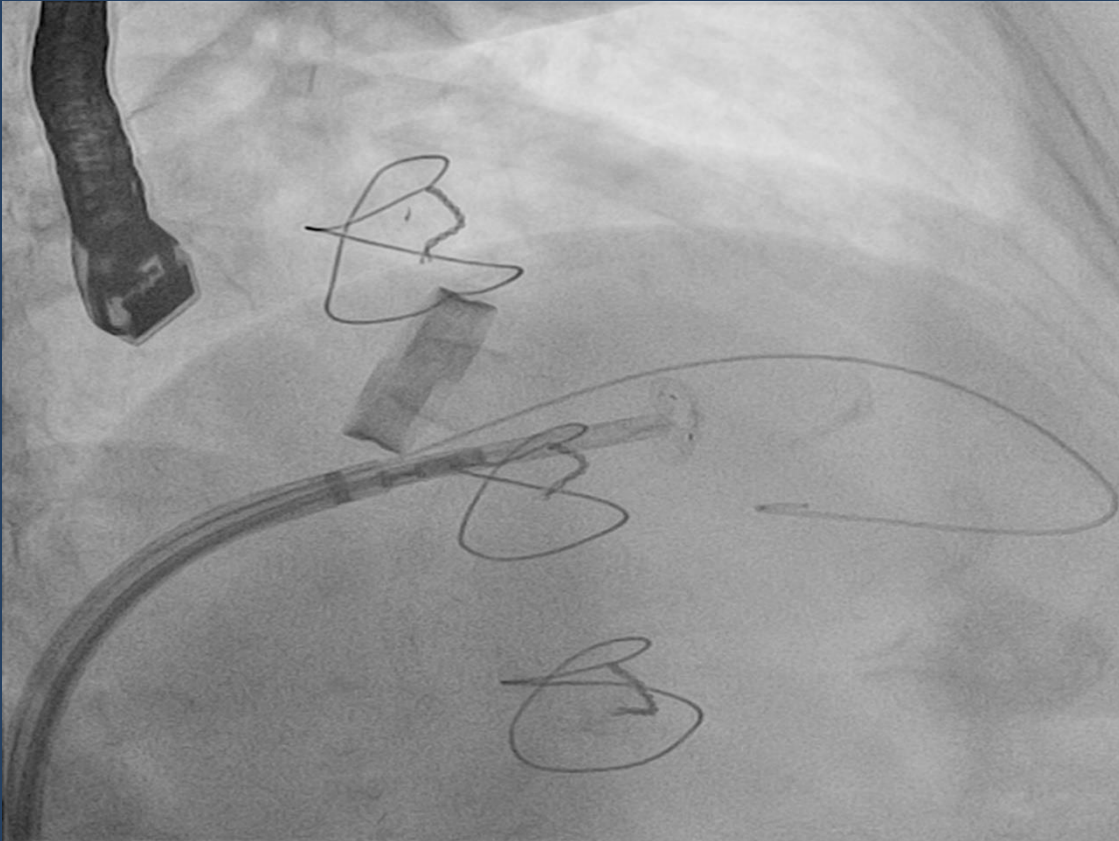
# Case example



Plug delivery and positioning



# Case example



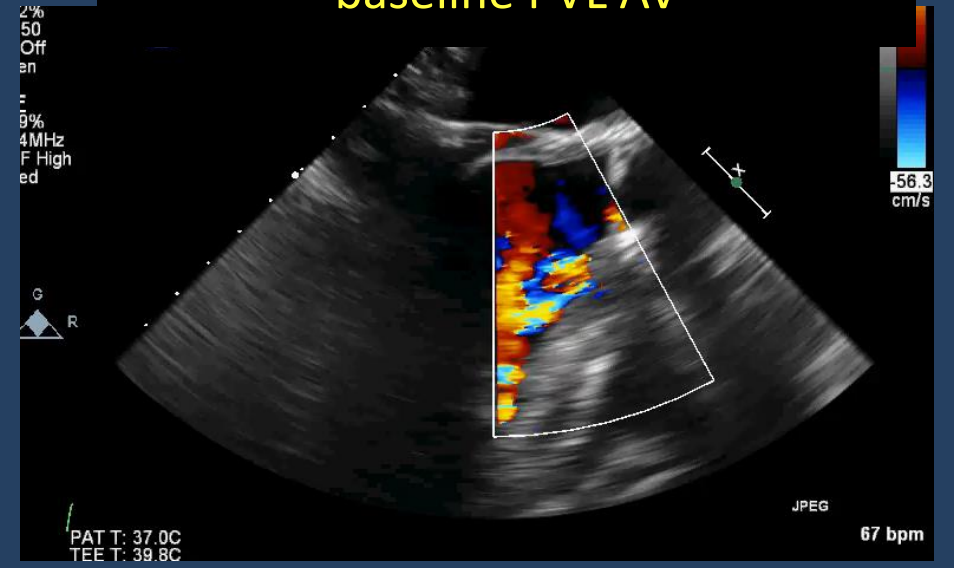
Plug delivery and positioning

# Multiplug approach

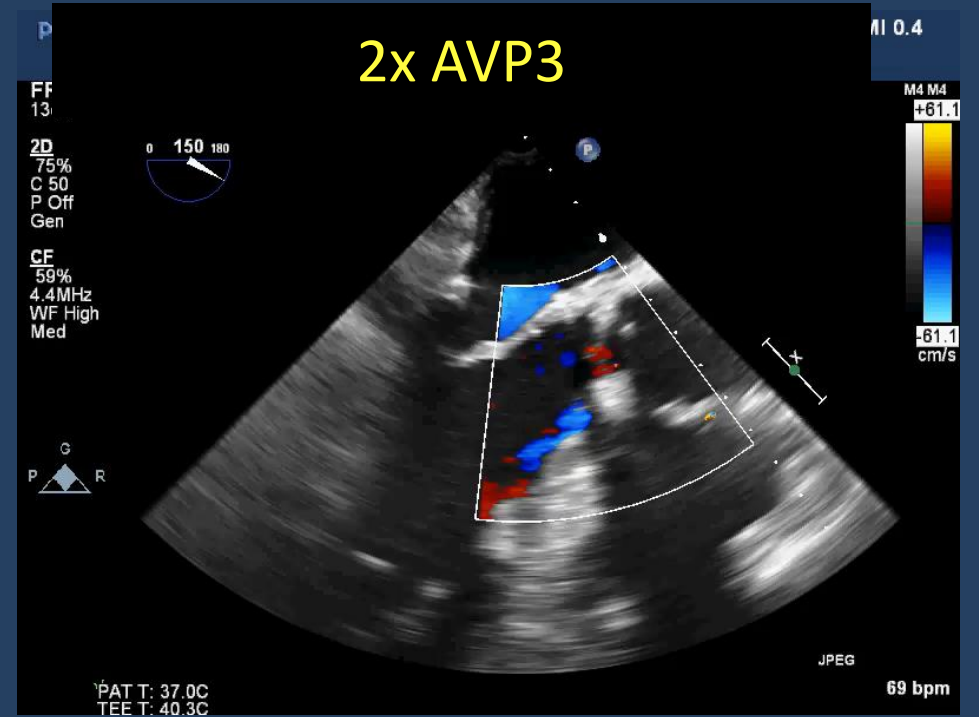
3D Beats 4Q



baseline PVL AV

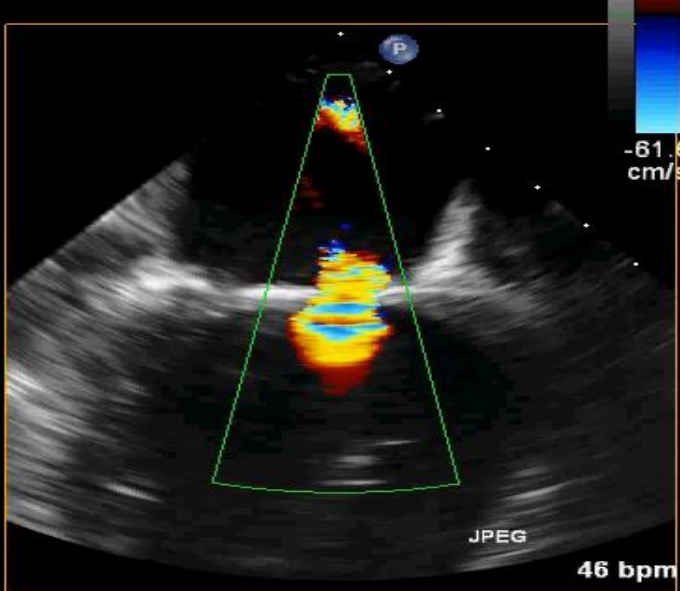
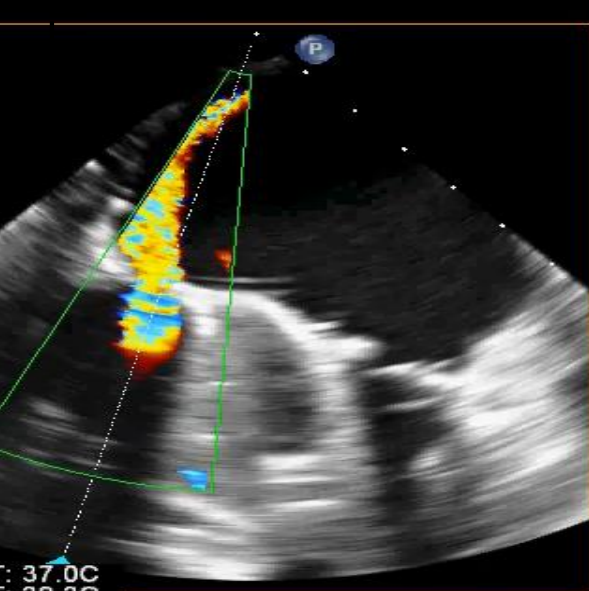
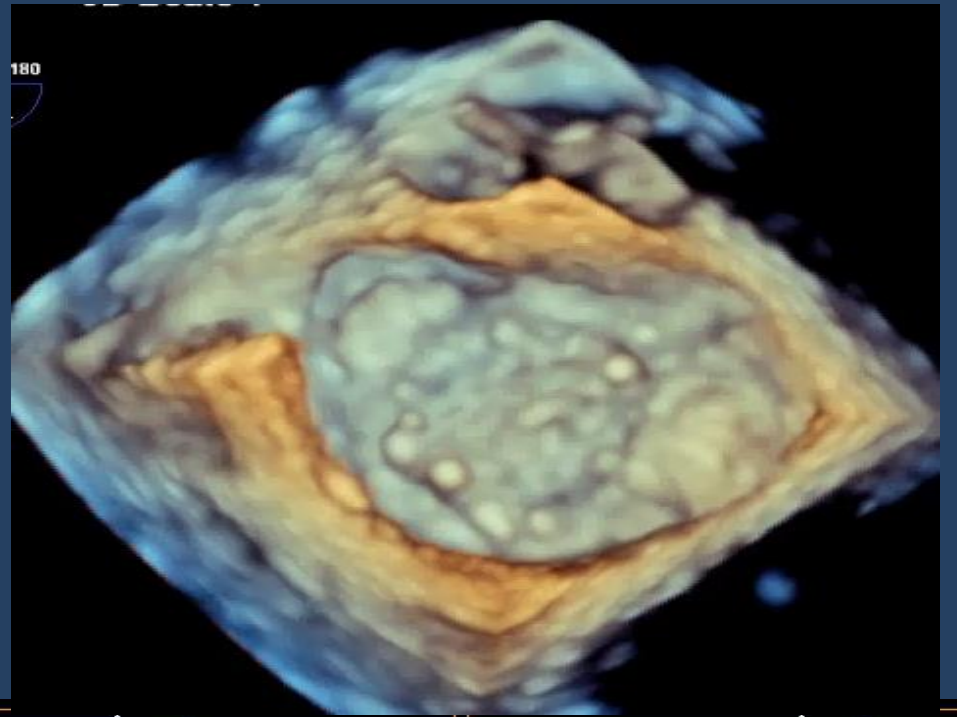


2x AVP3



# PLD device

TECHNOLOGY



# Registry data

## Multiplug Paravalvular Leak Closure Using Amplatzer Vascular Plugs III: A Prospective Registry

Grzegorz Smolka,<sup>1\*</sup> MD, Piotr Pysz,<sup>2</sup> MD, Marek Jasiński,<sup>3</sup> MD, PhD, Tomasz Roleder,<sup>2</sup> MD, Ewa Peszek-Przybyła,<sup>1</sup> MD, Andrzej Ochala,<sup>1</sup> MD, PhD, and Wojciech Wojakowski,<sup>1</sup> MD, PhD

TABLE II. Procedure Details

	Paramitral	Paraaortic
Numer of leaks	29	20
Numer of procedures	34	20
Second attempt after failed procedure	5	–
Transapical	9 <sup>a</sup>	
Number of leaks with 2/3/4 implanted plugs	13/14/2	14/6/0
CSA of simultaneously implanted in one PVL plugs (mm <sup>2</sup> )	68 [95%CI: 60.9–96.0, min. 26, maks.280)	36 (95%CI: 32.0–47.6, min. 12, max.53)
PVL CSA (mm <sup>2</sup> )	47 (95%CI: 39.1–55.5, min. 10, max. 165)	24 (95%CI: 21.2–26.8, min. 18.0–82.0)
No more than mild residual leak after TPVLC	26	20

## Transcatheter closure of paravalvular leaks using a paravalvular leak device – a prospective Polish registry

Grzegorz Smolka<sup>1</sup>, Piotr Pysz<sup>2</sup>, Michał Kozłowski<sup>1</sup>, Marek Jasiński<sup>3</sup>, Radosław Gocoł<sup>3</sup>, Tomasz Roleder<sup>2</sup>, Agnieszka Kargul<sup>4</sup>, Andrzej Ochala<sup>1</sup>, Wojciech Wojakowski<sup>1</sup>

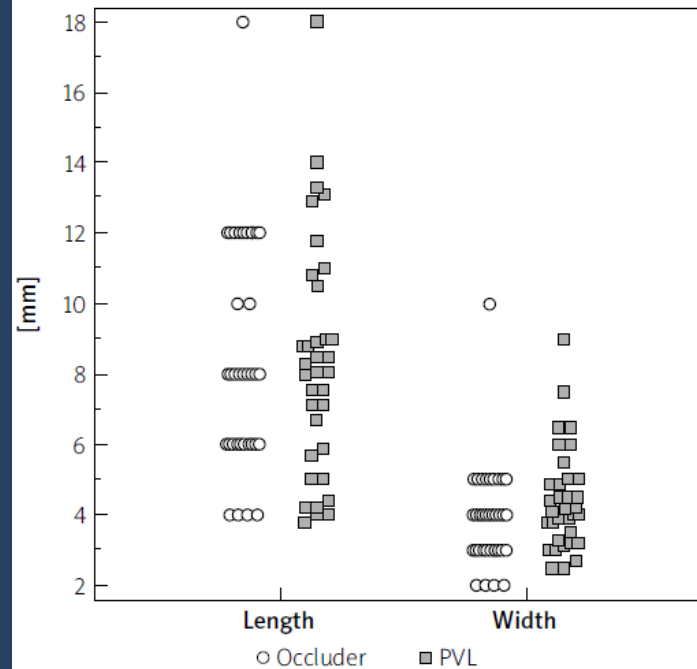


Figure 4. Correlation between the sizes of implanted PLDs and PVLs' dimensions (length and width of CSA) by RT 3D TEE

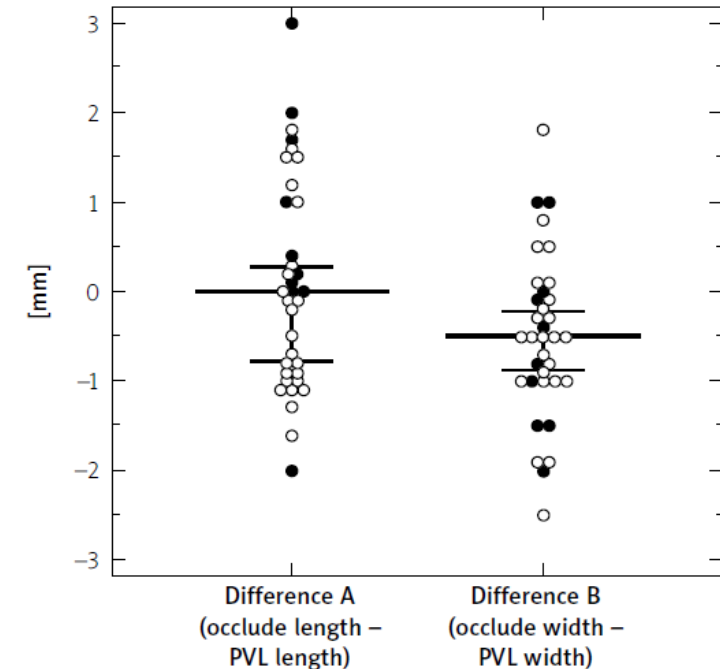


Figure 5. Influence of device oversizing on residual flow presence (filled circles) or absence (empty circles)

# Registry data

## Transcatheter paravalvular leak closure and hemolysis – a prospective registry

Grzegorz Smolka<sup>1</sup>, Piotr Pysz<sup>1</sup>, Andrzej Ochała<sup>1</sup>, Michał Kozłowski<sup>1</sup>, Wojciech Zasada<sup>2,3</sup>, Zofia Parma<sup>1</sup>, Michał Tendera<sup>1</sup>, Wojciech Wojakowski<sup>1</sup>

Variable	Reduction of CSA < 90% N = 16	Reduction of CSA ≥ 90% N = 59	P-value
$\Delta$ HGB <sub>discharge – 1 month</sub> [g/dl]	0.7 ±1.1 0.7 (0.2–0.9)	1.3 ±1.0 1.2 (0.5–2.0)	0.0365
$\Delta$ HGB <sub>baseline – 6 months</sub> [g/dl]	0.0 ±1.8	1.6 ±1.6	0.0020
$\Delta$ RBCC <sub>discharge – 1 month</sub> [M/mm <sup>3</sup> ]	0.2 ±0.3 0.1 (–0.1 – 0.4)	0.5 ±0.3 0.5 (0.2–0.7)	0.0007
$\Delta$ RBCC <sub>baseline – 6 months</sub> [M/mm <sup>3</sup> ]	–0.1 ±0.7 0.0 (–0.9 – 0.4)	0.6 ±0.5 0.6 (0.2–0.9)	0.0003
$\Delta$ LDH <sub>discharge – 1 month</sub> [IU/l]	48.9 ±260.5 38.0 (36.8–108.0)	8.9 ±181.4 3.0 (–88.0 – 73.0)	0.3512
$\Delta$ LDH <sub>baseline – 6 months</sub> [IU/l]	–164.9 ±577.3 –6.0 (–290.0 – 117.0)	–296.9 ±508.1 –173.0 (–487.0 – 28.0)	0.2547

## Improved Transseptal Access for Transcatheter Paravalvular Leak Closure Using Steerable Delivery Sheaths: Data From a Prospective Registry

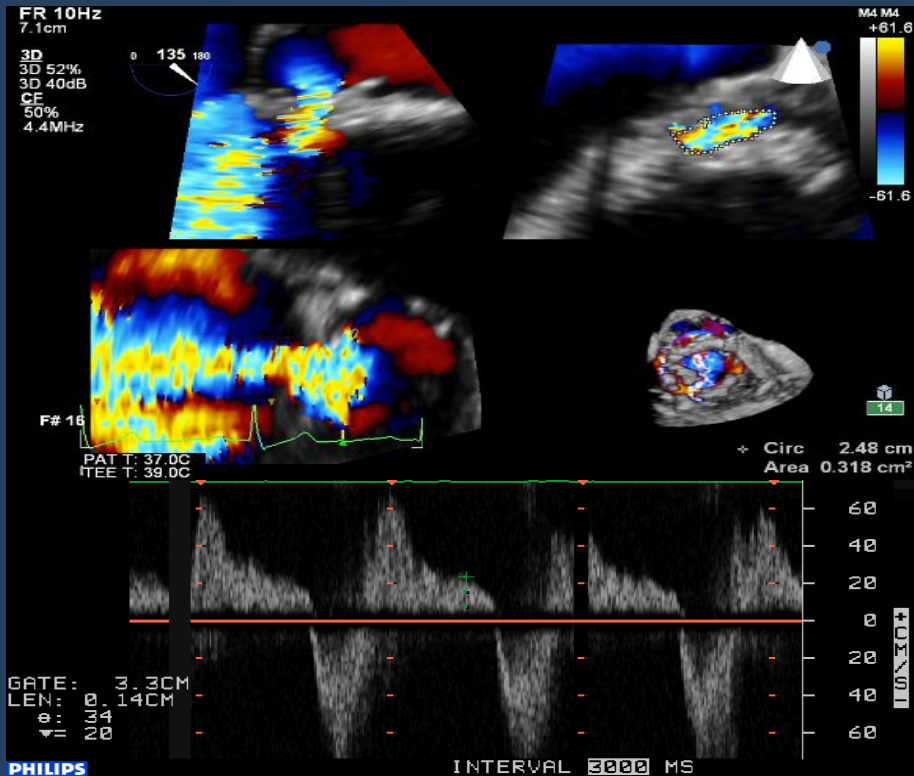
Michał Kozłowski, MD, PhD<sup>1</sup>; Piotr Pysz, MD<sup>2</sup>; Wojciech Wojakowski, MD, PhD<sup>1</sup>; Grzegorz Smolka, MD<sup>1</sup>

Implantation time (minutes)	28.5 [15–58]	64 [35–180]	<.05
Technical success rate	29 [93.5%]	16 [72.7%]	<.05
PVL location			
Anterior	10 [32.2%]	7 [31.8%]	NS
Medial	11 [35.5%]	8 [36.3%]	NS
Posterior	3 [9.7%]	4 [18.1%]	NS
Lateral	7 [22.6%]	3 [13.6%]	NS
Procedural failures	1	2	NS
Failure to cross the PVL	1	1	NS
Valve interference	0	1	NS
Total number of implanted devices	47	42	NA
Number of implanted PLDs	29	9	NA
Number of implanted AVP III devices	18	32	NA

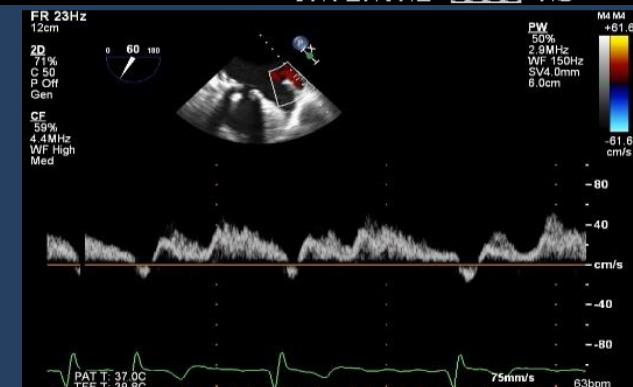
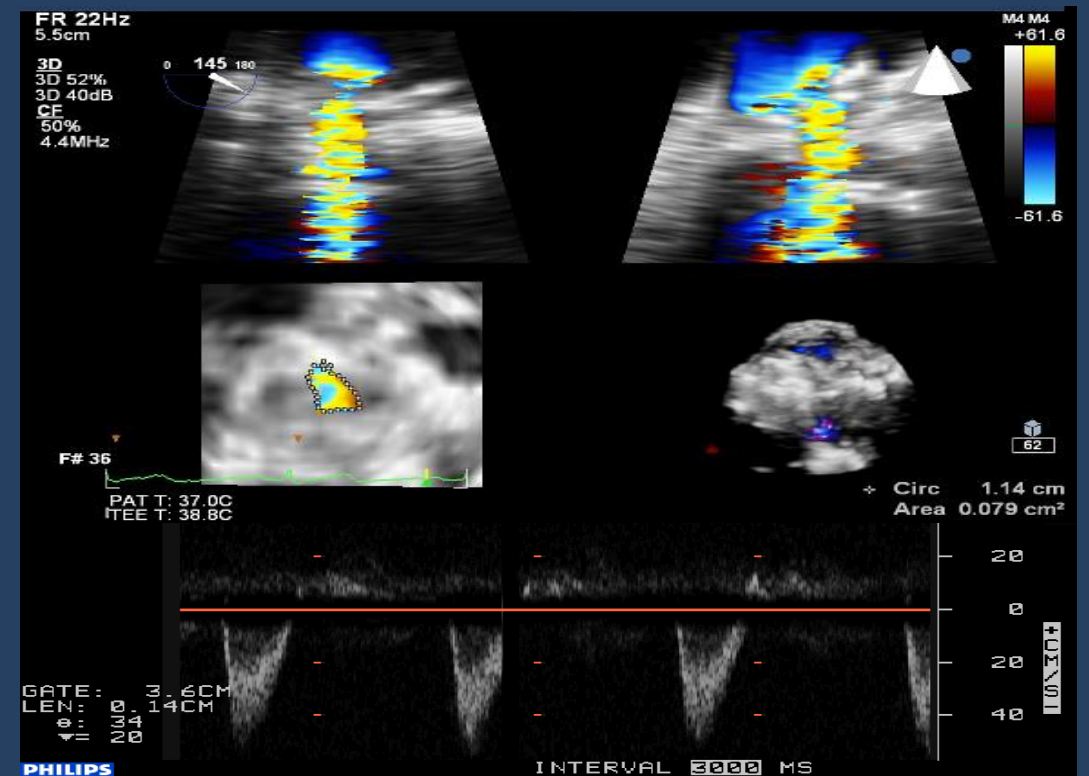
Other predictors: mitral location, calcifications

# Post procedural assessment and follow-up

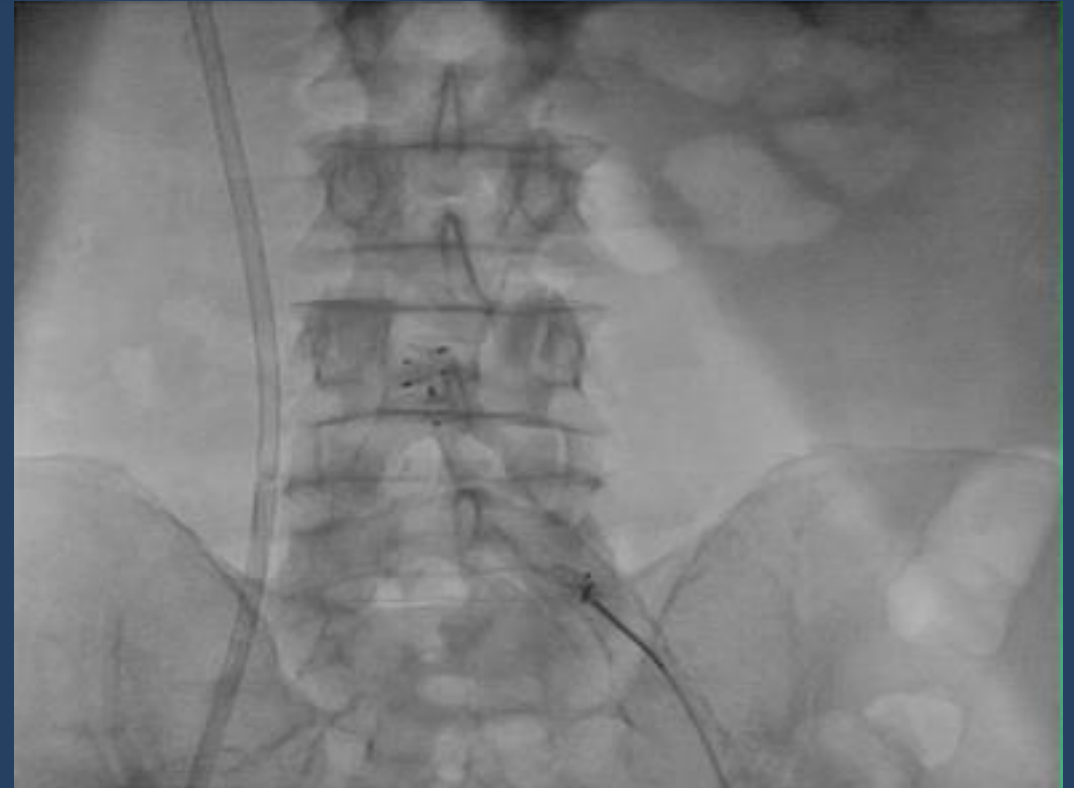
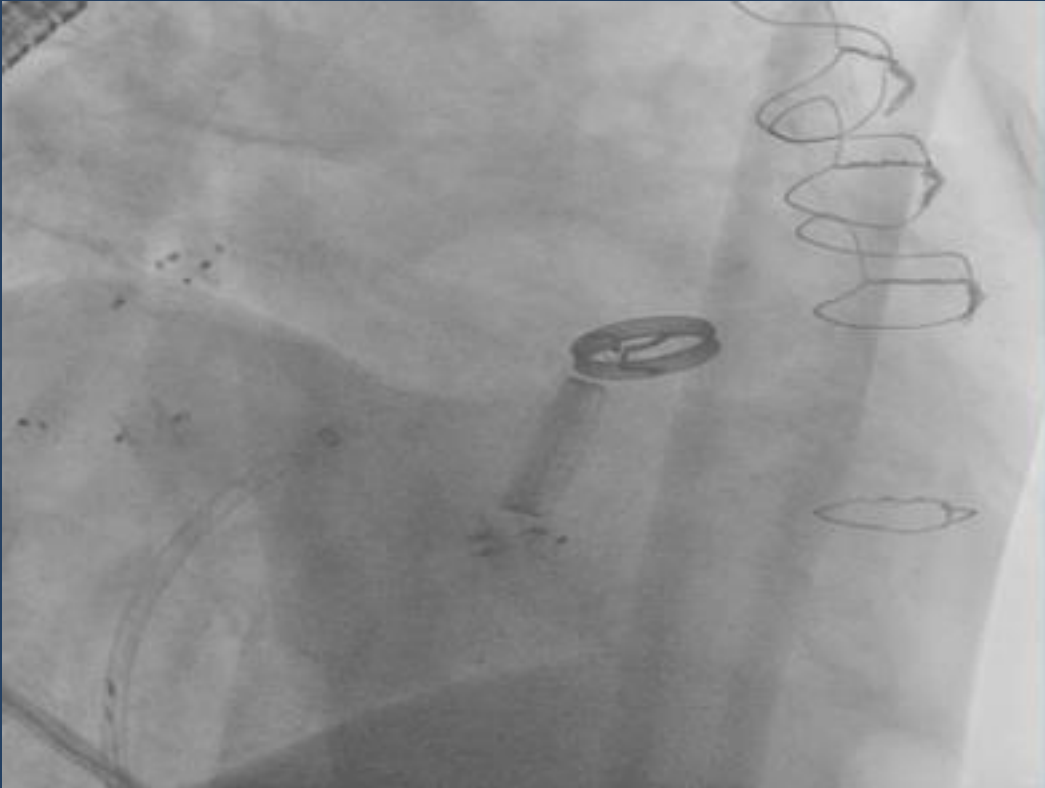
## Baseline



## Post procedure



# Troubleshooting



Snare

Large deflectable sheaths

## Conclusions

- Clinical assessment: HF, hemolysis, exclusion of infectious endocarditis
- Transcatheter closure of PVL is preferred treatment for patients with HF or hemolytic anemia
- In majority of cases multiple plugs are necessary
- COMBO approach with large deflectable sheaths improves mitral PVL closure
- Optimal toolbox (delivery sheaths, guidewires, catheters, snares)
- TOE is a must preferably with 3D reconstruction
- Residual/recurrent leak and hemolysis (PVL can reoccur)
- Incomplete closure, even if reducing HF symptoms, may result in worsening of hemolysis
- Dedicated device which provides complete sealing is needed



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# Transcatheter Paravalvular Leak Closure

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Michał Tendera  
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 Springer