Post-operative evaluation and complication management

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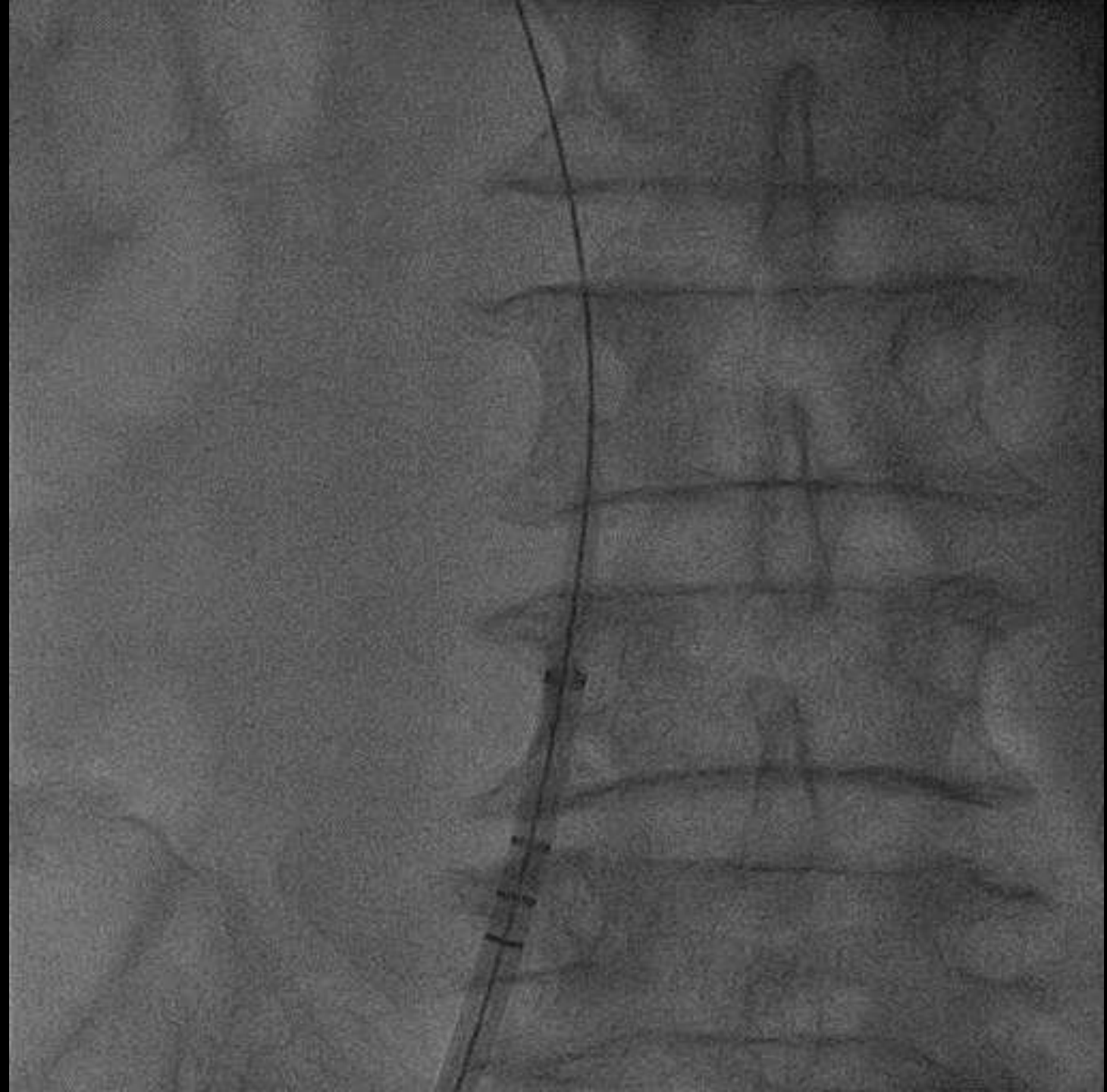
Access site complications

- Arterial puncture / pseudoaneurysm
  - Give fluids if dry
  - Use ultrasound if difficult
- Access site bleeding
  - Perclose device (Proglide)
  - Hemostatic stitch
  - Warfarin / heparin 4-6 hours later, only when hemostasis secured
- Venous perforation
  - Prepare the skin and subcutaneous tissue well with blunt dissection
  - Slowly advance delivery sheath, rotating the catheter


1
2
3
4cm


1
2
3
4cm



The hemostatic stitch – a cost-effective way to secure hemostasis

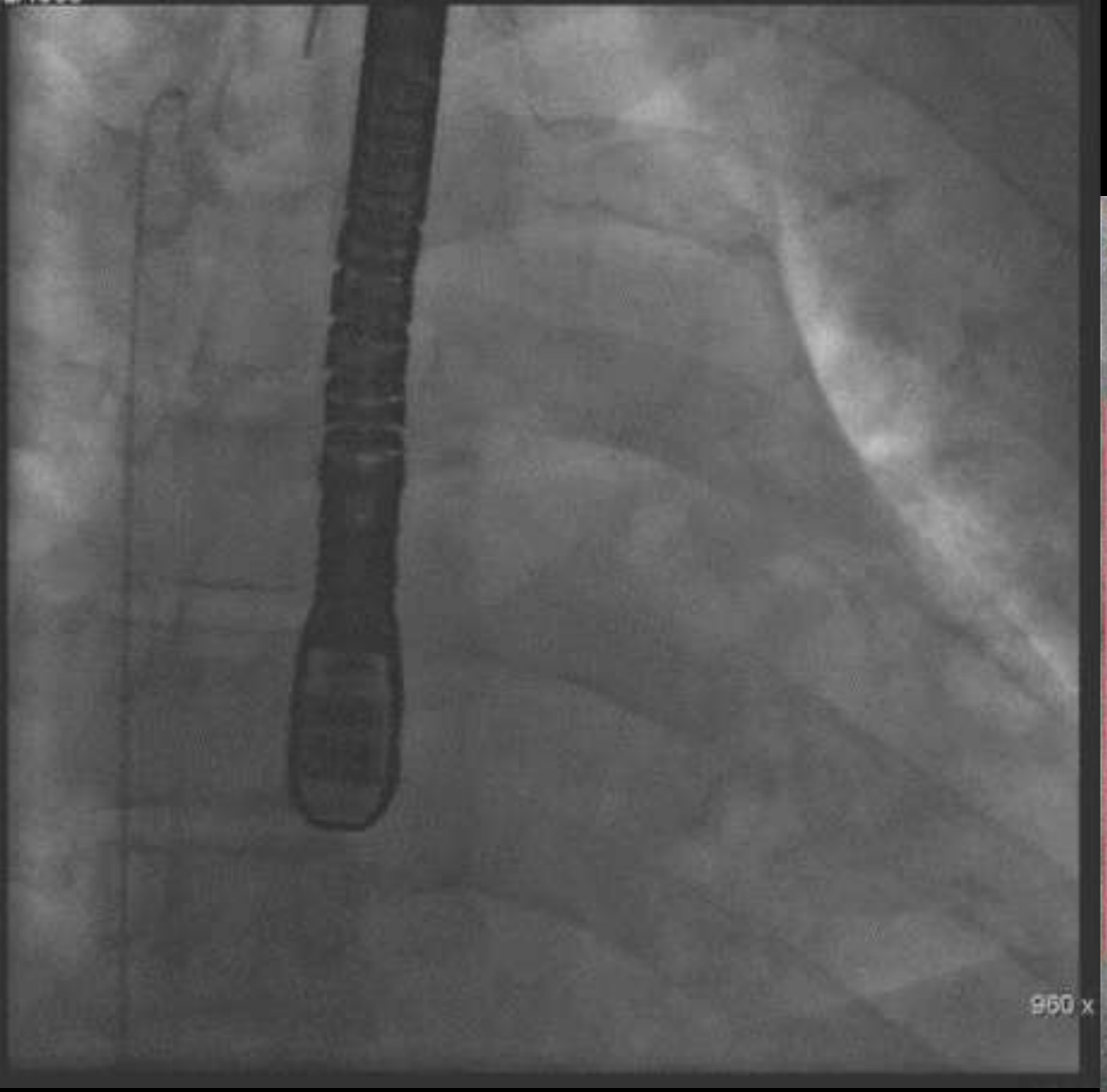
Cardiac perforation

- Use ICE or TEE guidance to know where your materials are in the LA

- By the sheath
  - Never push the sheath in the LA too much, unguided by a wire in the LUPV

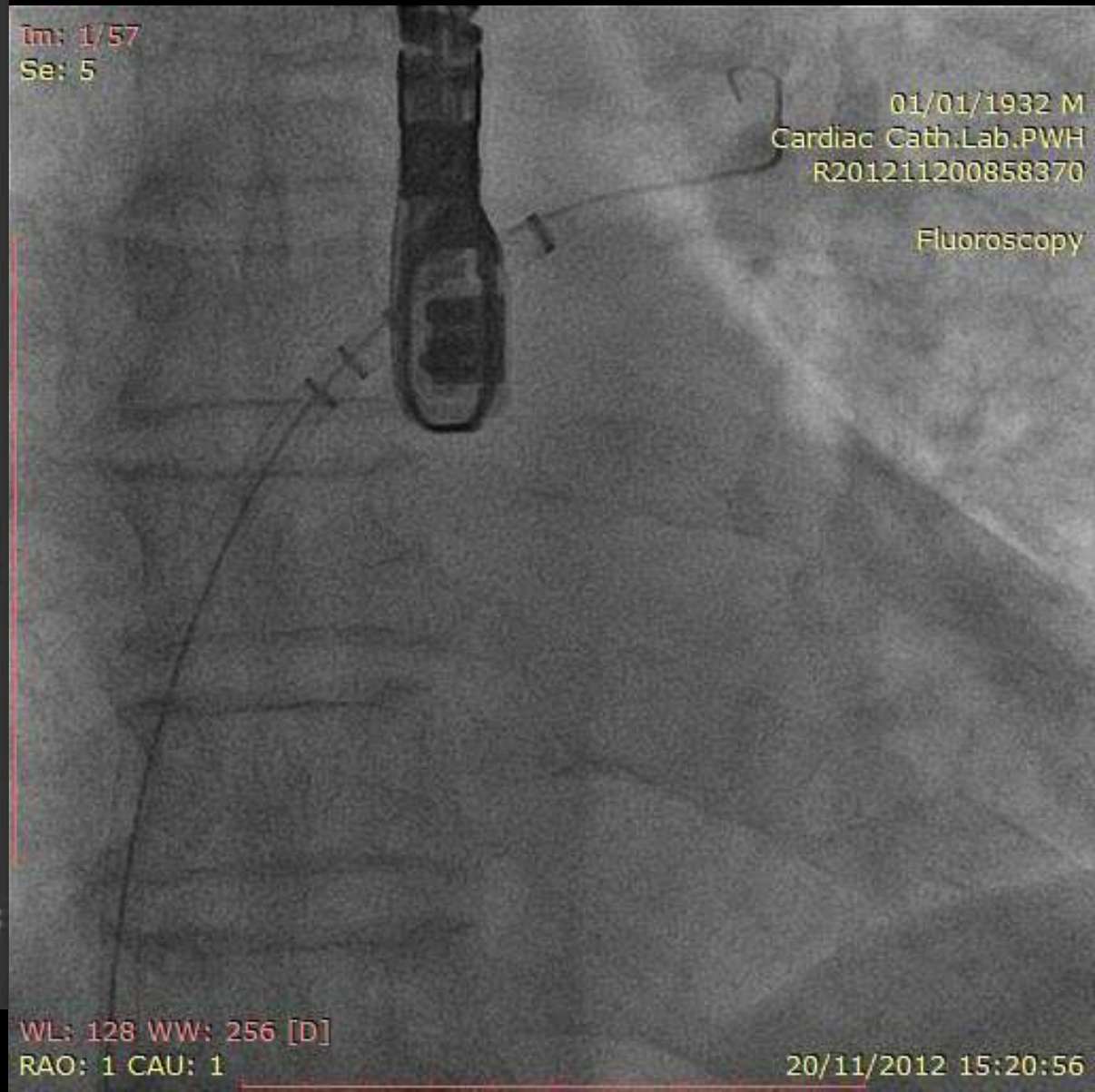
- By the wire
  - Know what a wire in the LAA looks like
  - Know what a wire in the LUPV looks like – it is outside the cardiac border

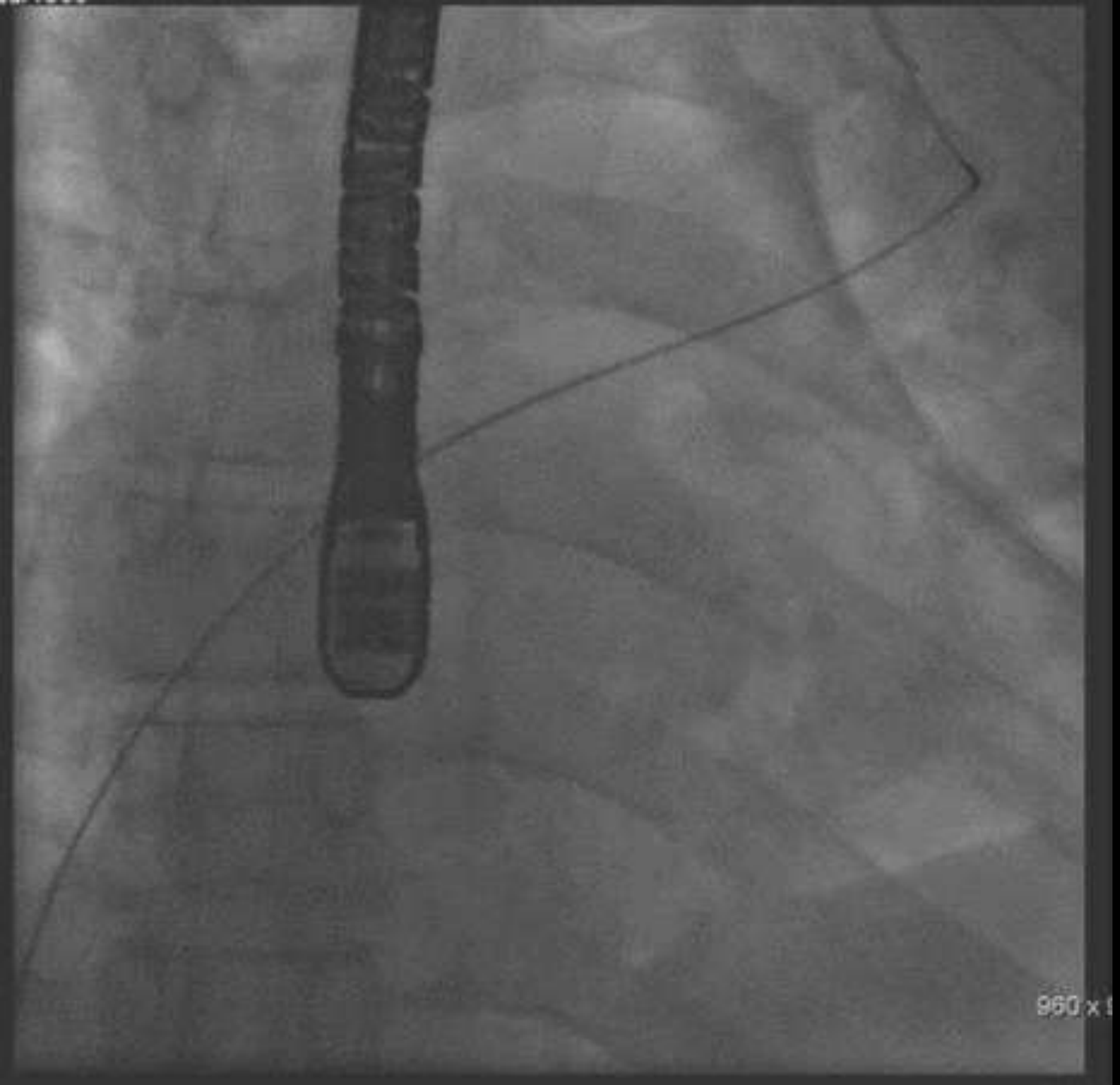
- By the device
  - The Gore occlude has a sharp point when initially exteriorized from the sheath



LAA? Or LUPV? Use an MPA2 to direct the wire

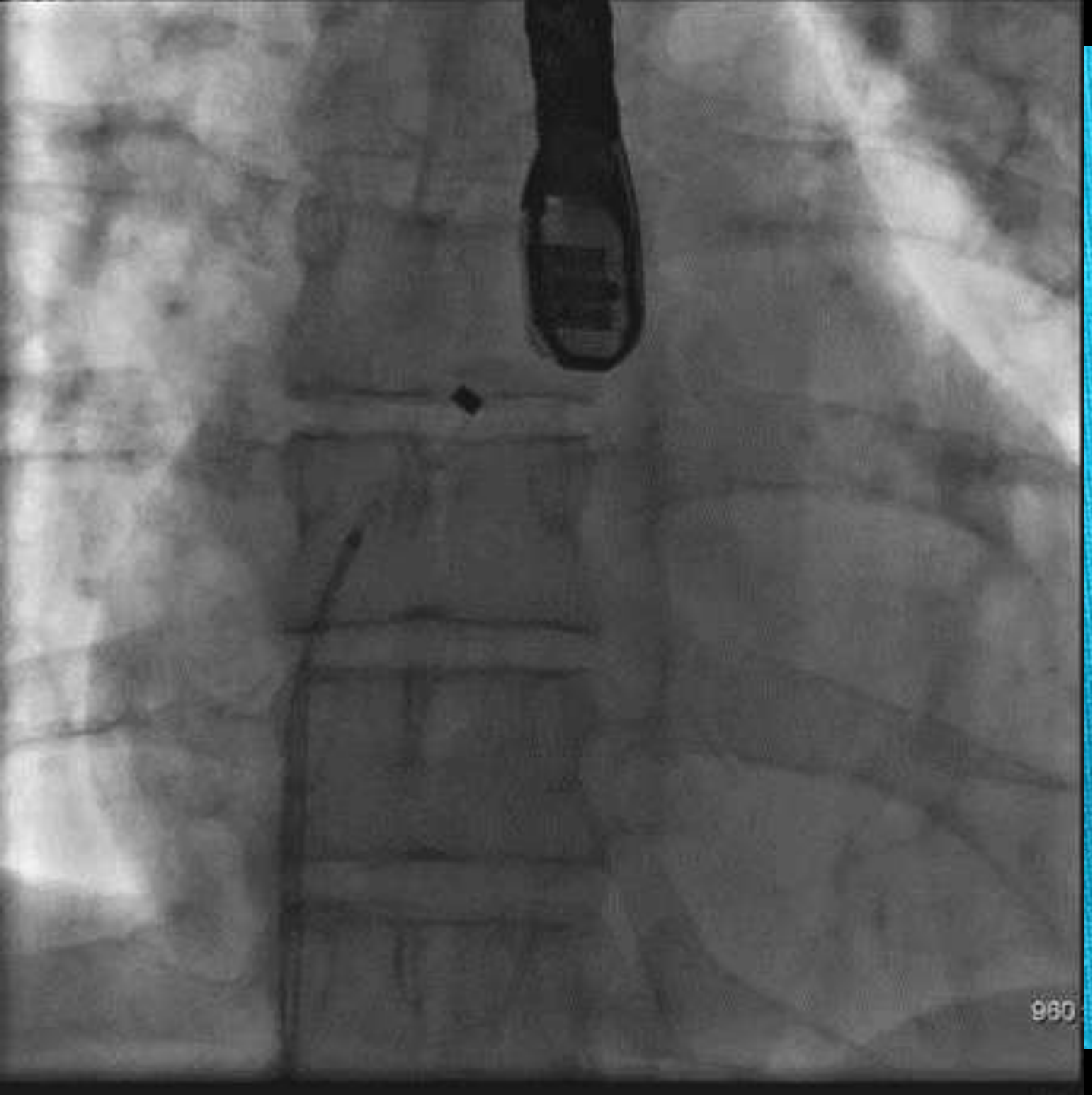
How not to manipulate a wire in the LUPV

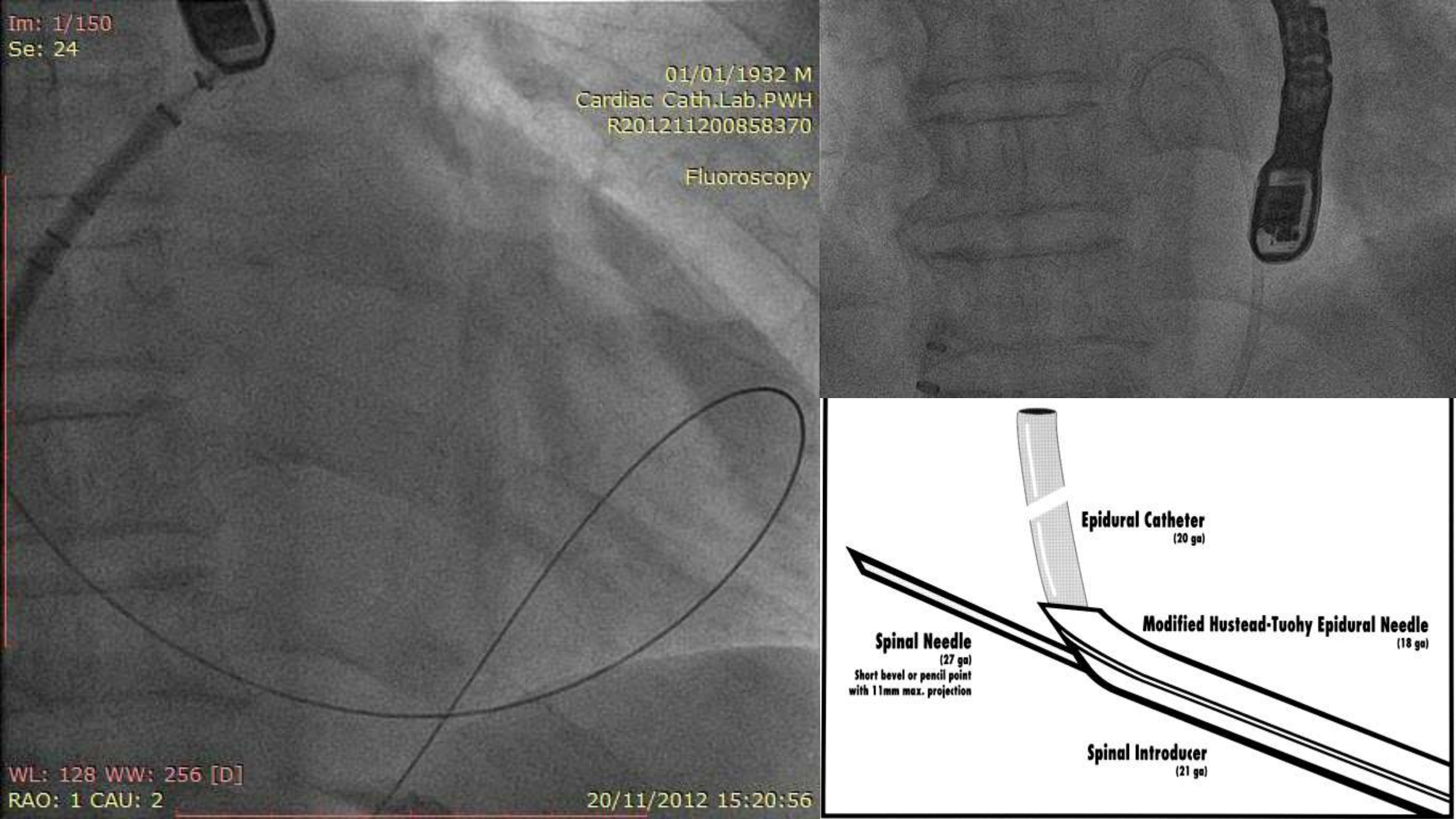




With the wire securely in the LUPV, the delivery sheath can be safely advanced into the LA

In this case the Gore delivery sheath is a monorail design

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Fluoroscopy
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Epidural Catheter
(20 ga)
Modified Hustead-Tuohy Epidural Needle
(18 ga)
Spinal Needle
(27 ga)
Short bevel or pencil point
with 11mm max. projection
Spinal Introducer
(21 ga)

Air embolism

- Can cause myocardial ischemia
- Can cause cerebral infarctions

Prevention

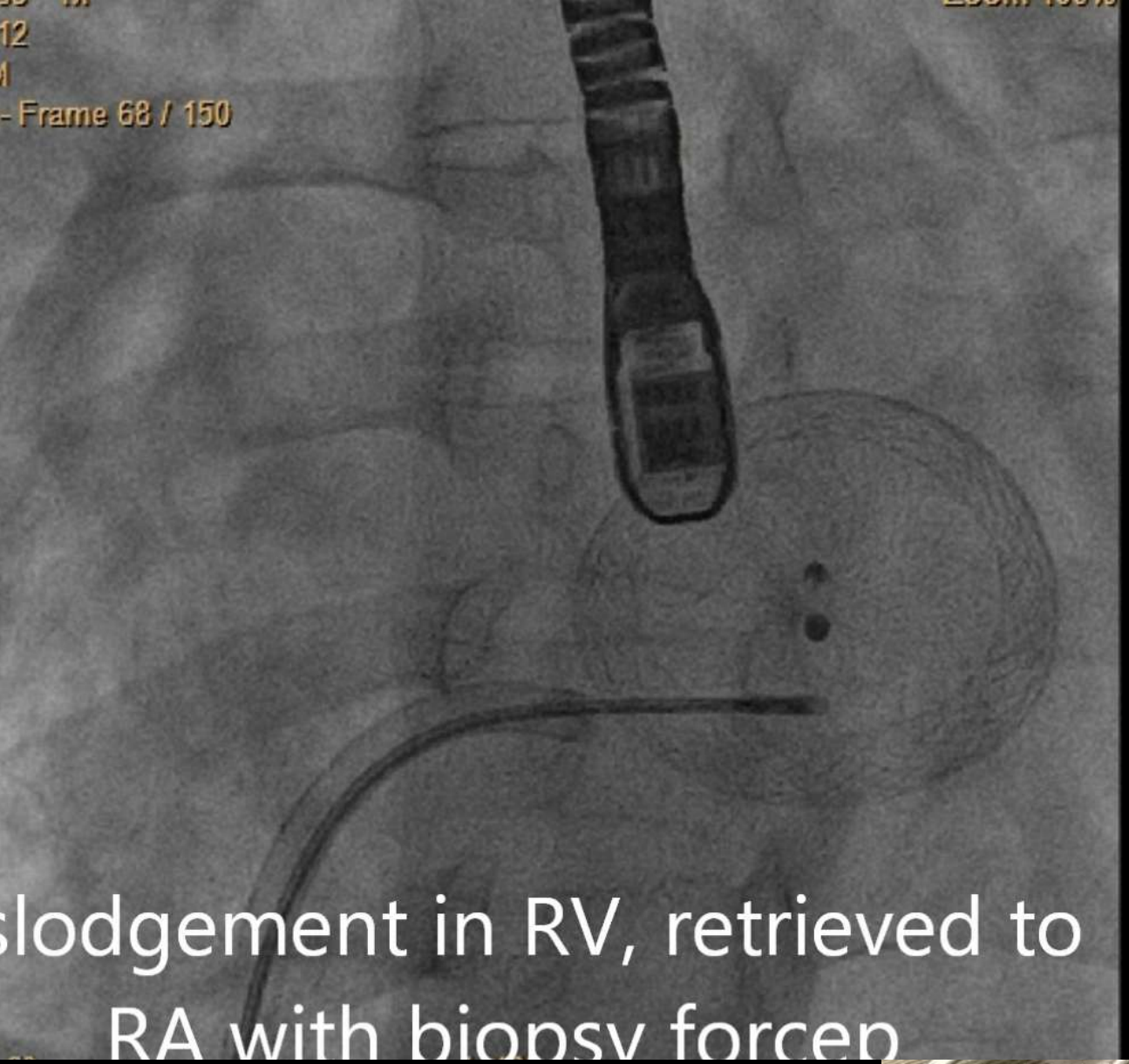
- Meticulous de-airing bleed-back of big sheaths
- Underwater advancement of device into sheath (avoid venture effect)
- Slow advancement of device in sheath


De-airing under the level of the LA

Continuous saline flushing whilst device is advanced

Dislodgement

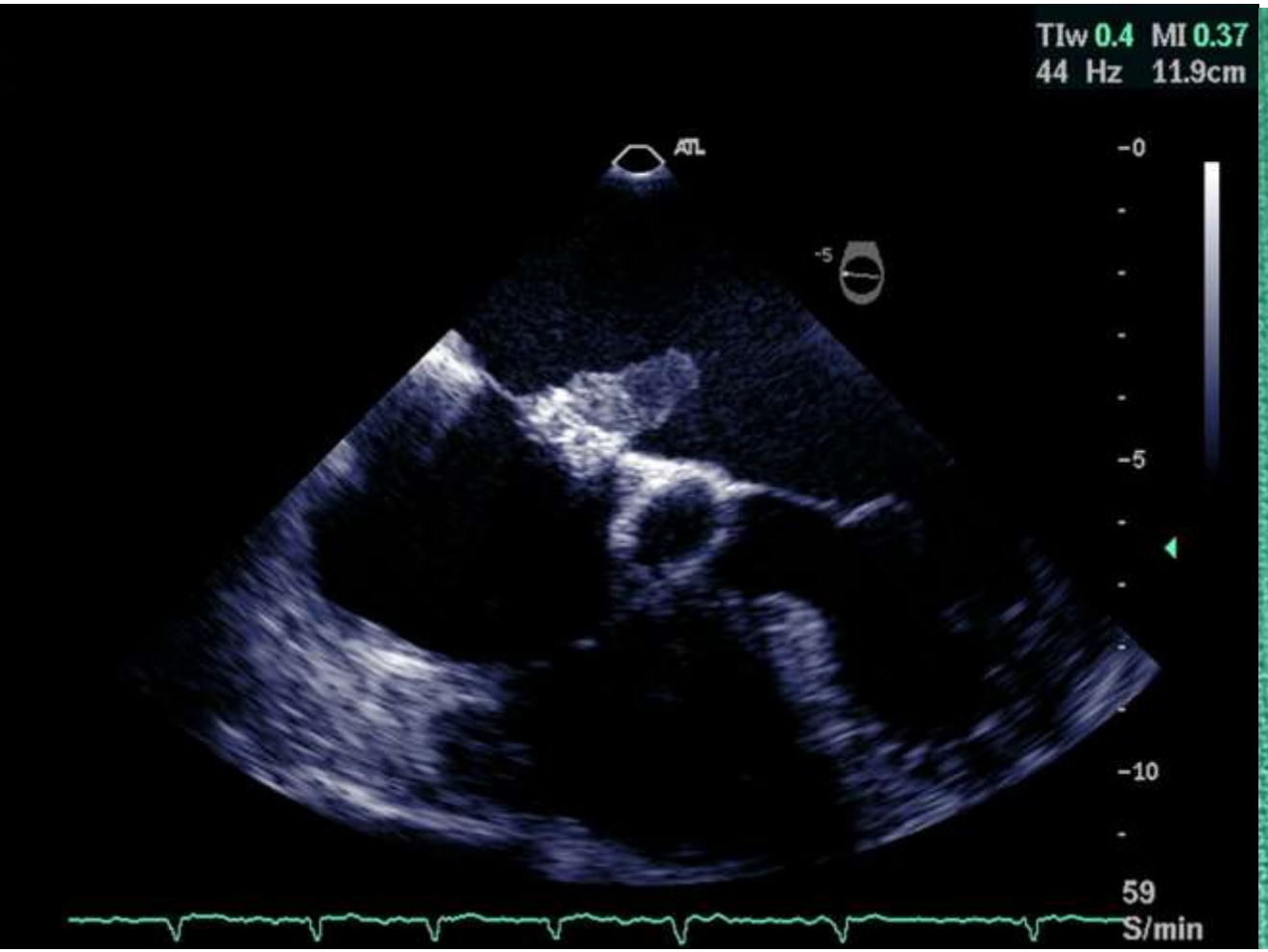
- ……..thankfully rare because PFOs have very small waists and the device is generally very firmly held in-place



slodgement in RV, retrieved to
RA with biopsy forcep

Thrombus on device and embolisation

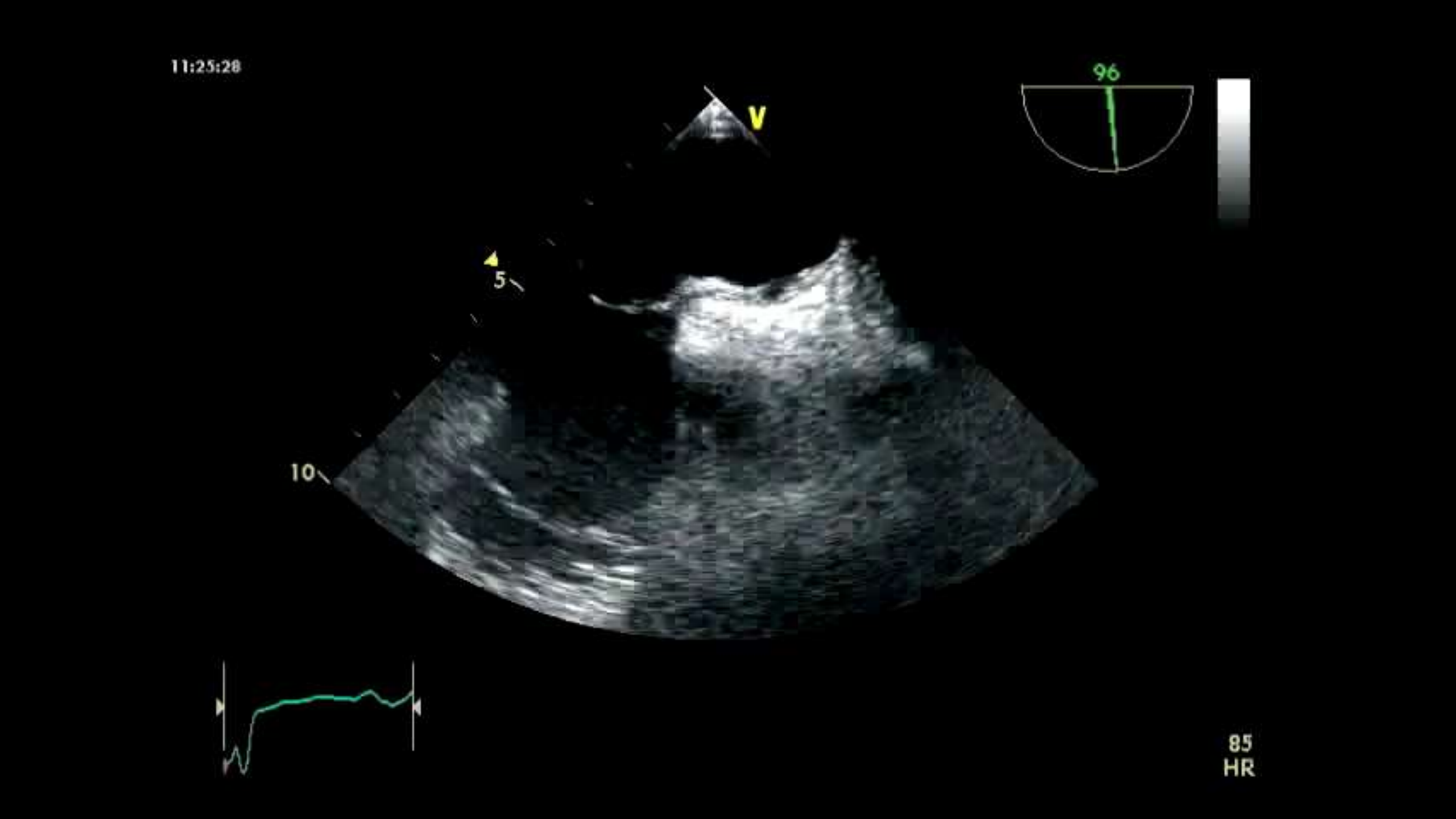
- 2-10% in combined PFO/ASD occluder literature
- Treated with warfarinisation for 2-3 months
- Re-imaging (TEE) usually shows resolution of the thrombus



Dimitar Divchev et al. Eur J Echocardiogr 2007;8:53-56

Other important complications

- New Atrial fibrillation 2 - 6% vs. 0.7 - 1.5% with MT
- Residual shunt – effective closure 86% - 93% (grade 1 or less shunt at 6 month TEE)
- Both of these cause STROKE, which is why the procedure was performed in the first place


11:25:28
96
V
5
10
85
HR

Trial	Events	Intervention group (%)	Medical therapy (%)	Hazard ratio	Confidence interval (95% CI)	*P*-value
PC trial	New-onset atrial fibrillation	6 (2.9) Two transient, 2 required pharmacological cardioversion, 1 required electrical cardioversion, and 1 sustained AF	2 (1)	3.15	0.64–15.6	0.16
	Myocardial infarction	2 (1)	1 (0.5)	2.04	0.19–22.5	0.62
	Hospital admission related to patent foramen ovale	13 (6.4)	13 (6.3)	1.02	0.48–2.21	0.95
	Bleeding	8 (3.9)	12 (5.7)	0.66	0.27–1.62	0.40
	Vascular procedural complication	2 (1)	N/A	N/A	N/A	N/A
CLOSURE 1	New-onset atrial fibrillation	23 (5.7) Only 14 during the initial 30 days of follow-up, it was transient in 17 patients and persistent in 6 patients	3 (0.7)	N/A	N/A	<0.001
	Major bleeding episode	10/378 (2.6)	4/374 (1.1)	N/A	N/A	0.11
	Death other than endpoint	2 (0.5)	4 (0.9)	N/A	N/A	0.51
	Nervous system disorder	6 (1.5)	16 (3.5)	N/A	N/A	0.15
	Vascular procedural complication	8 (1.7)	N/A	N/A	N/A	N/A
	Cardiac perforation	1 (0.2)	0	N/A		
RESPECT	New-onset atrial fibrillation	(3)	(1.5)	N/A	N/A	N/A
	Pulmonary embolism	6 (1.2)	1 (0.2)	N/A	N/A	0.12
	Major bleeding episode	8 (1.6)	9 (1.9)	N/A	N/A	0.81
	Vascular procedural complication	3 (0.6)	0	N/A	N/A	0.124
	Cardiac perforation	1 (0.2)	0	N/A	N/A	0.124

Rengifo-Moreno P et al.
Eur Heart J. 2013 Nov;34(43):3342-52

Post-procedural follow-up

- Monitor groin wound overnight
- Transthoracic echo next day to verify device in-situ
- Discharge with aspirin 80mg and clopidogrel 75mg daily
- Antibiotic prophylaxis for 6 months for high risk procedures (unless residual significant shunt, in which case this is lifelong)
- TEE at 6 months to look at residual shunt and thrombus
- If satisfactory then stop clopidogrel and continue aspirin lifelong

Conclusions

- PFO closure is a safe procedure with a very low complication rate
- But it is only as safe as the technique of the operator
- Complications can be anticipated and prevented easily
- The simplest mis-step can make life hell later (arterial puncture)