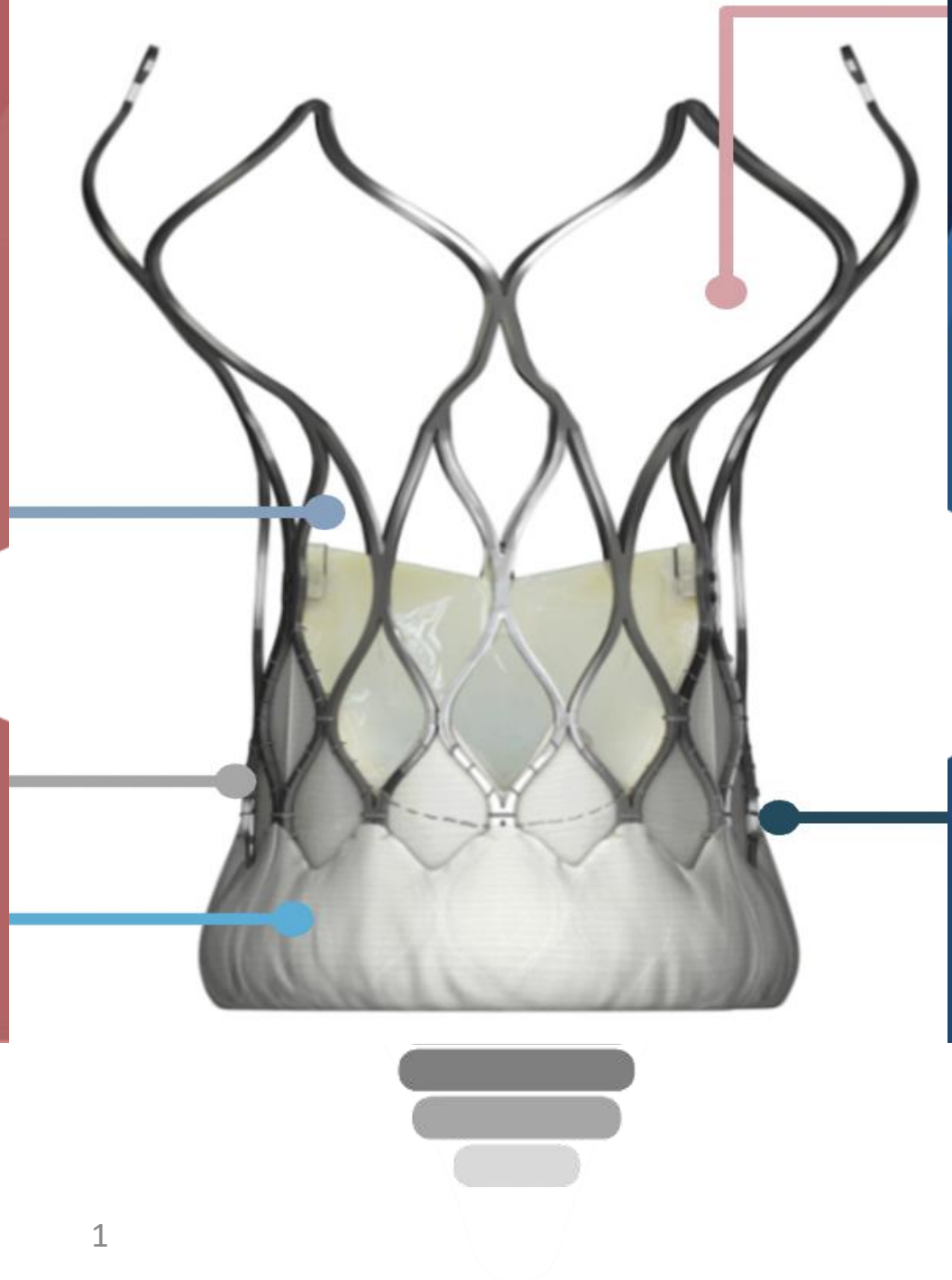

VitaFlow I TAVI System techniques & tips

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VitaFlow™

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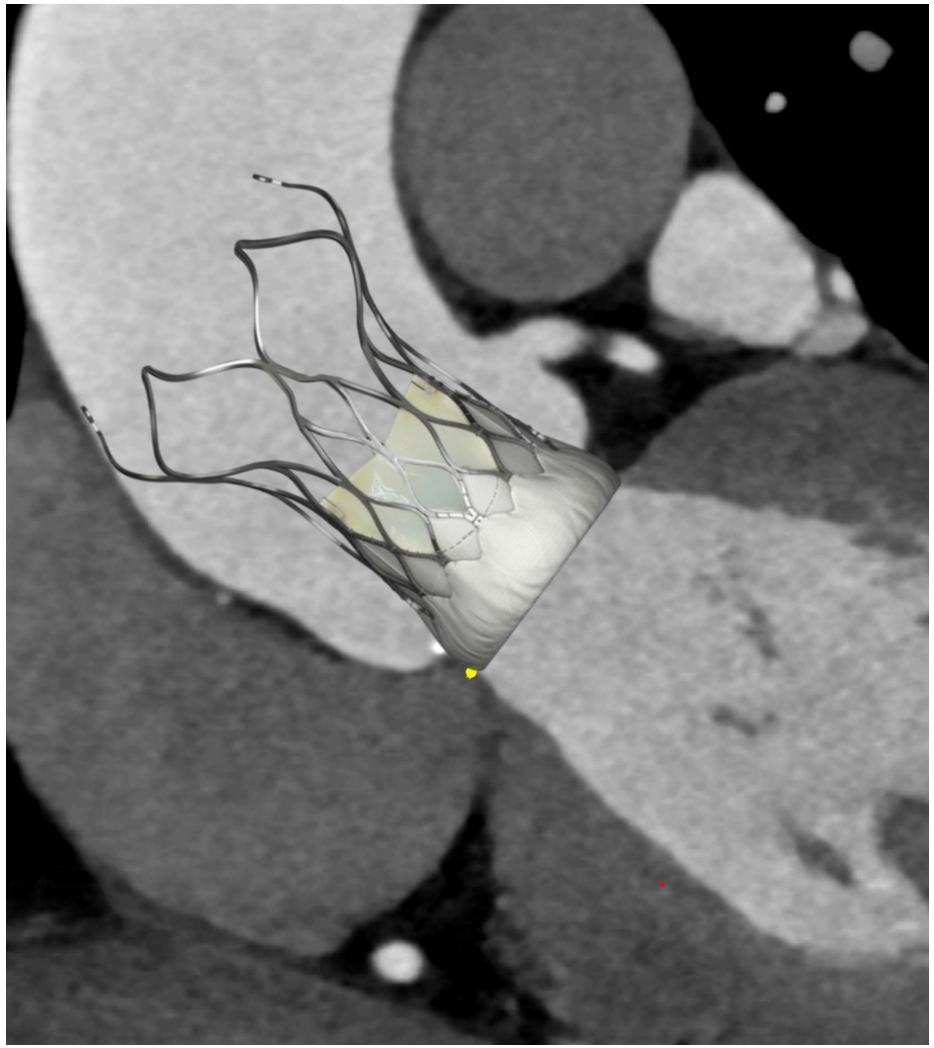
- ❑ Procedure steps

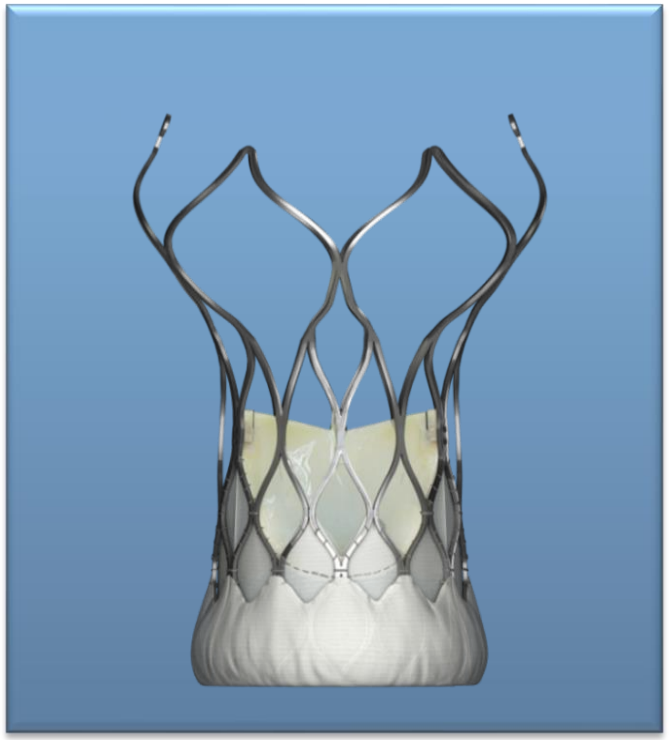
1. Vascular Access
2. Crossing the Aortic Valve
3. Balloon Aortic Valvuloplasty
4. System Insertion and Alignment
5. Bioprosthesis Deployment
6. Post Implant Assessment

- ❑ Individualized implant depth

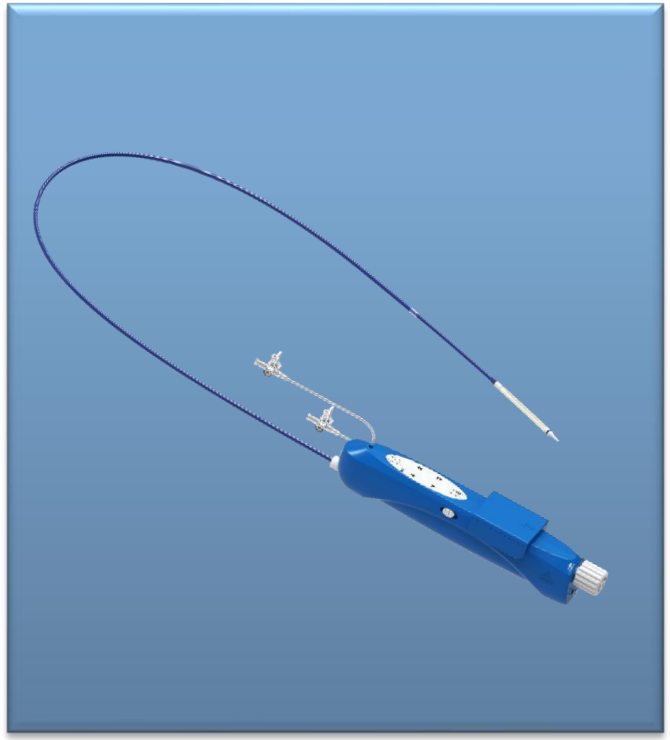


VitaFlow I Platform

Aortic Valve



Delivery System



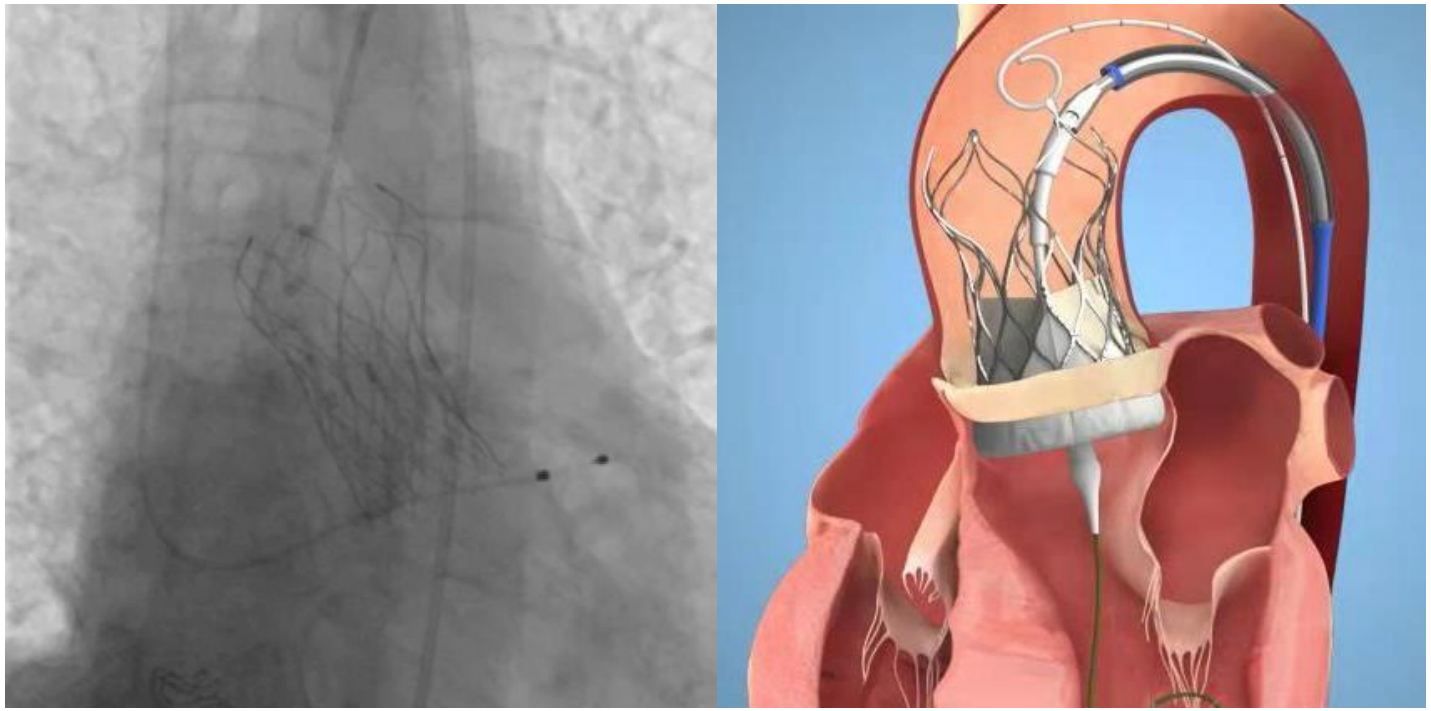
Balloon Catheter

Aortic valve design

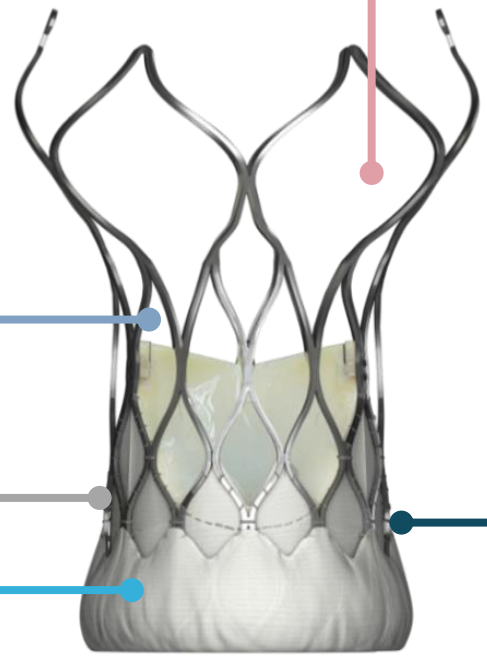
- ***Self-expandable nitinol frame***
- *Conforms and seals to the annulus*
- *Proven fatigue performance*
- *Allows for big strain during loading and recapture*

- ***Bovine pericardial leaflets***
- *Proven Long-term material*
- *Anti-calcification treatment*

- ***PET inner& outer skirt***
- *Reducing perivalvular leak and tissue damage*



Main features and clinical benefits



Low density cells

- *Easy bending when getting through aortic arch*
- *Providing excellent alignment*

Large cells

- *Enabling coronary access*

Supra-annular design

- *Delivering large EOAs and Low gradients*

Inner and outer skirt

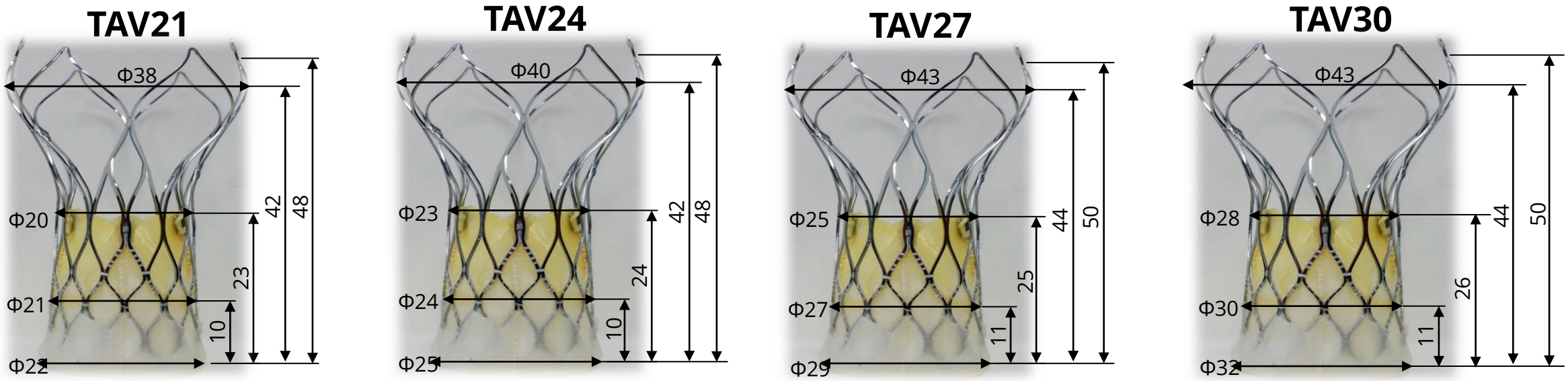
- *Reducing PVL*

High radial force frames

- *Able to dilate severe calcification or bicuspid valves*
- *Firm anchoring makes the valve position steady*

Device parameters

*VitaFlow I TAVI Systems treat the **annulus diameter range** from **17-29mm.***



Skirt height: 12mm,

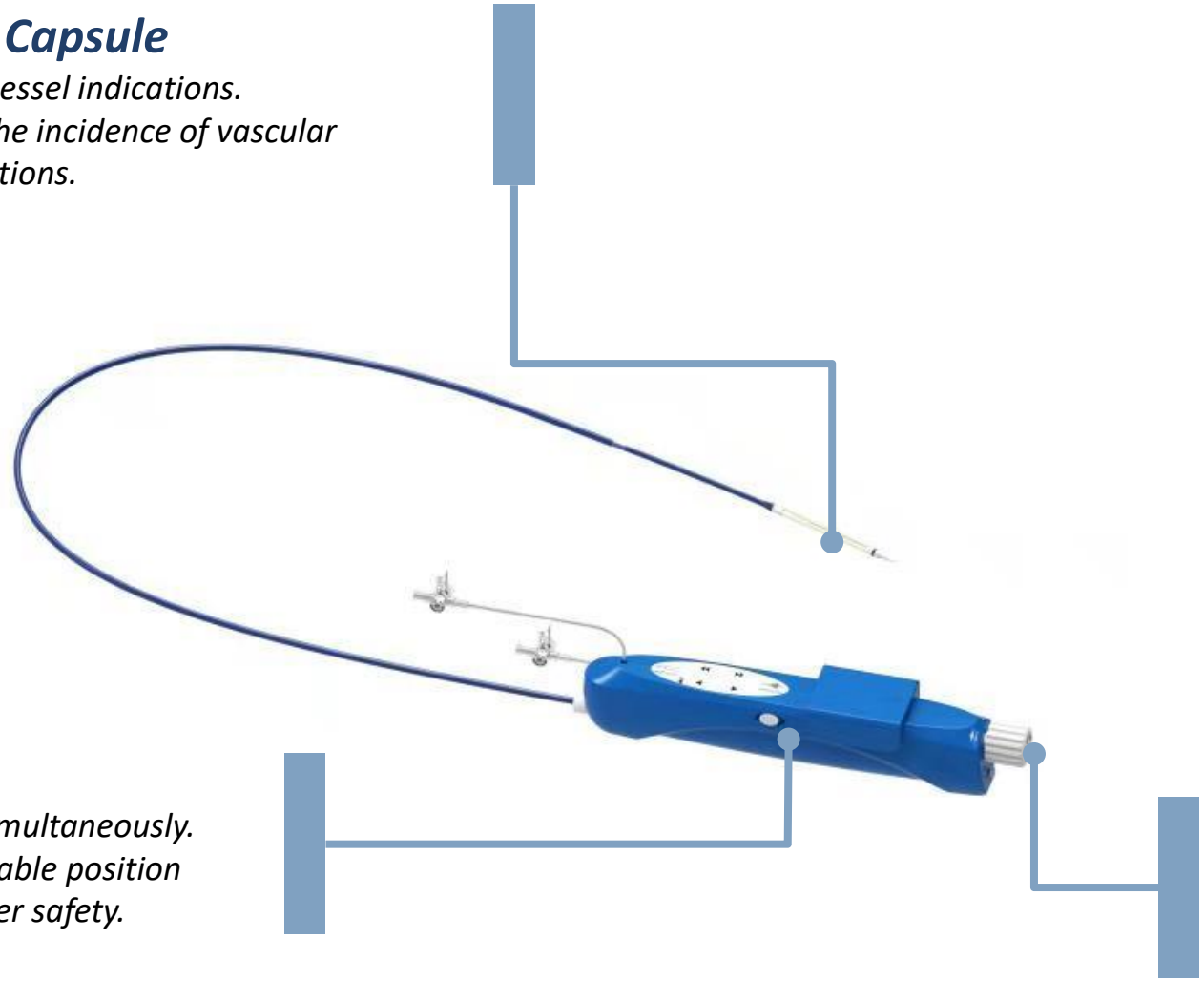
Frame height:48-50mm
(without paddles)

Model	TAV21			TAV24				TAV27			TAV30		
Diameter /mm	17	18	19	20	21	22	23	24	25	26	27	28	29
Perimeter/mm	**53.4**	**56.5**	**59.6**	**62.8**	**65.9**	**69.1**	**72.2**	**75.4**	**78.5**	**81.6**	**84.8**	**87.9**	**91.1**
Area/ mm^2	226.8	254.5	283.5	314.2	346.4	380.1	415.5	452.4	490.9	530.9	572.6	615.8	660.5

Features of delivery system

16F/18F Capsule

- *Expand vessel indications.*
- *Reduce the incidence of vascular complications.*



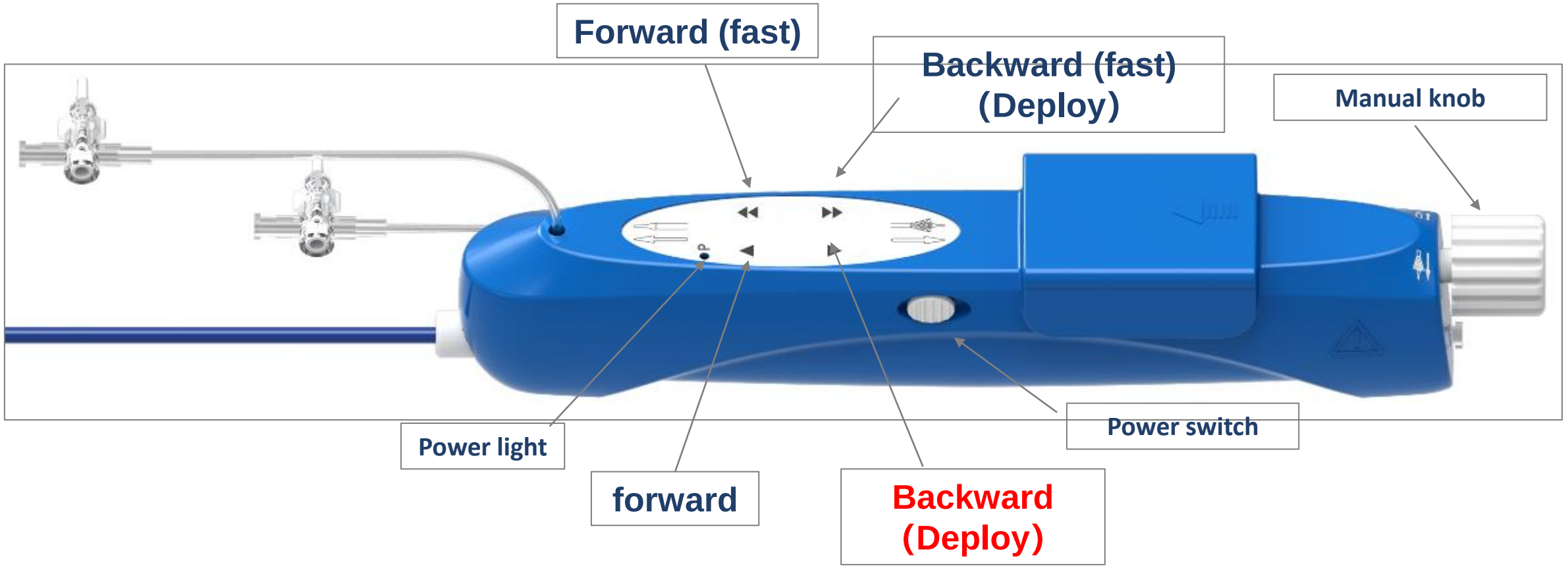
Motorized handle

- *Guide wire manipulation simultaneously.*
- *Helps with accurate and stable position during deployment for better safety.*

Manual knob

In case of malfunction of motorized handle

Handle


Forward (fast)
Backward (fast)
(Deploy)
Manual knob
Power light
forward
Backward
(Deploy)
Power switch

VitaFlow™ Valve Implantation steps

Vascular access

Advance a large sheath onto a super stiff guidewire (eg. Lunderquist) is recommended to prevent potential injury to the vascular of the patient.

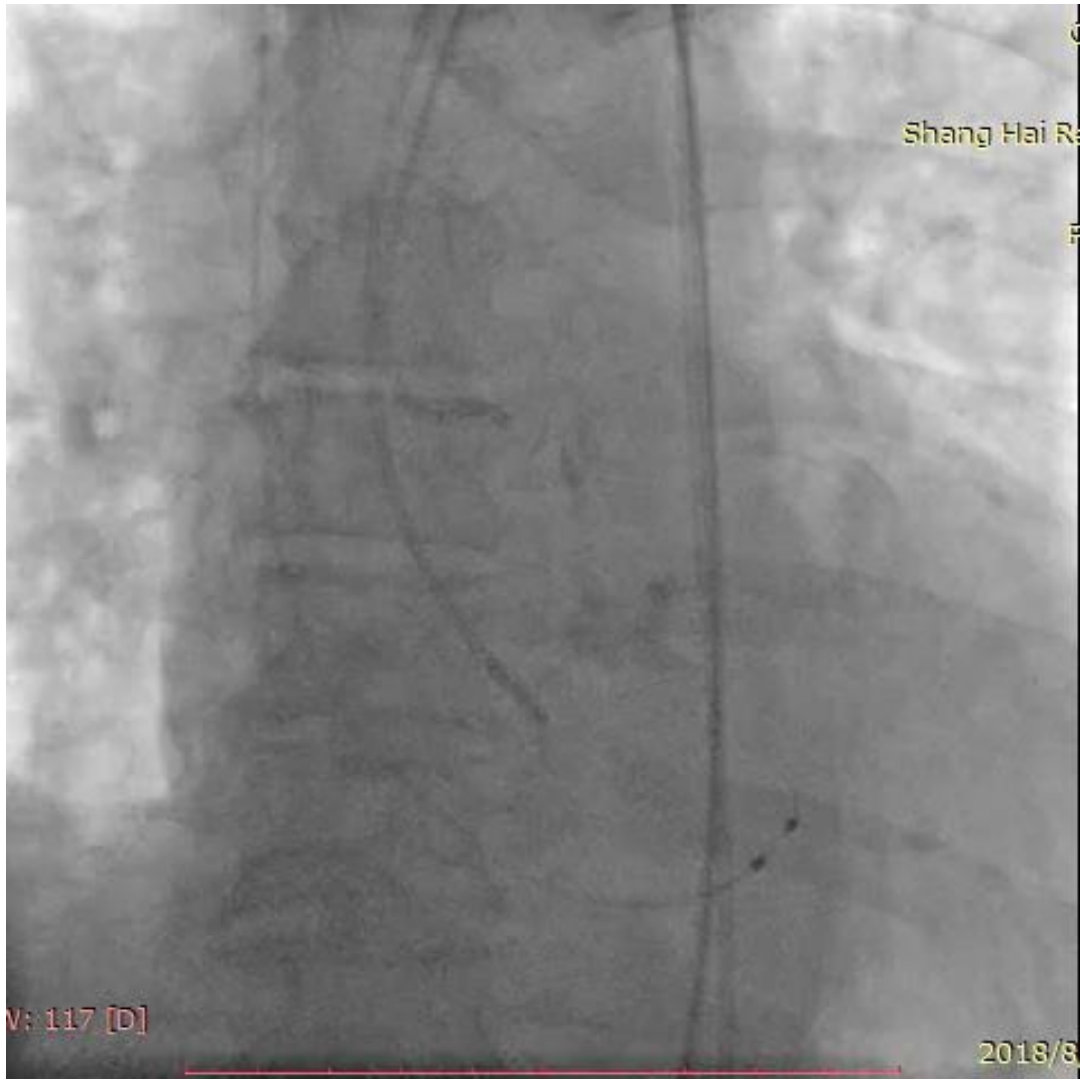
An 18F sheath fits for a 21 size VitaFlow valve, and 20F sheath for 24, 27, 30 size Vitaflow valve.

Then deliver the system along the super stiff guidewire.

If the access is heavily calcified, pre-dilate the vessels using a 12F up to a 16Fr dilator before inserting.

Cross the native valve

- Cross the native valve with an 0.035" straight tip guide-wire through an angiographic catheter
- Once in the left ventricle, advance the angiographic catheter and exchange the straight-tip guidewire for an exchange-length J-tip guidewire
- Exchange the angiographic catheter for a 6-Fr pigtail catheter and remove the wire to record the aortic pressure gradient



Perform Balloon Aortic Valvuloplasty (BAV)

Advance the balloon over the guidewire and position within the native annulus

- Begin rapid pacing and inflate balloon after pressure has dropped
- Deflate balloon and stop pacing
- Ensure that pressure rebounds and retrieve balloon from patient

Vascular access : cross aortic arch and native valve

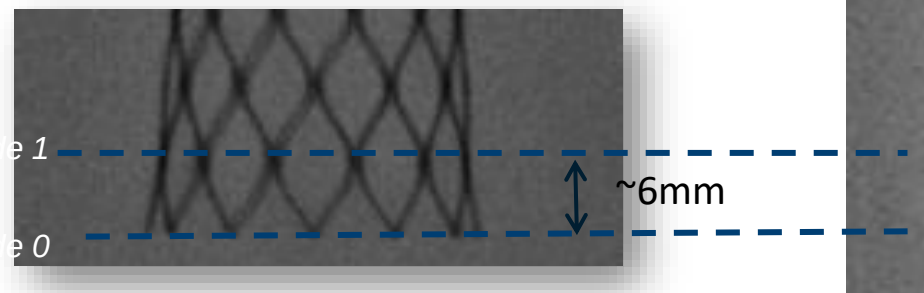
- ***Fluoroscopic surveillance of arch and wire in LV.***

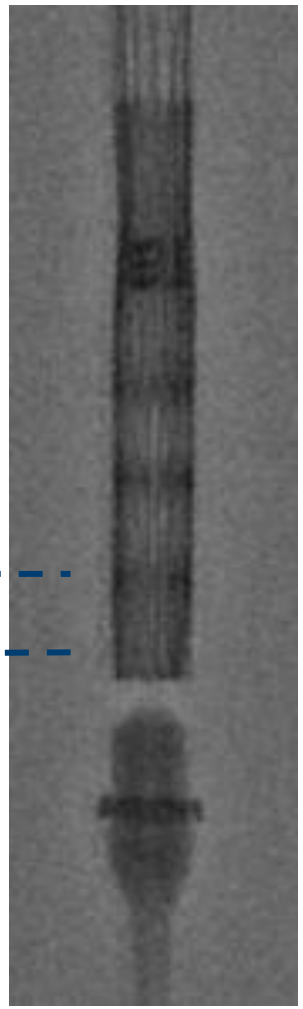
- ***Immediately stop advancing if excess resistance is encountered.***

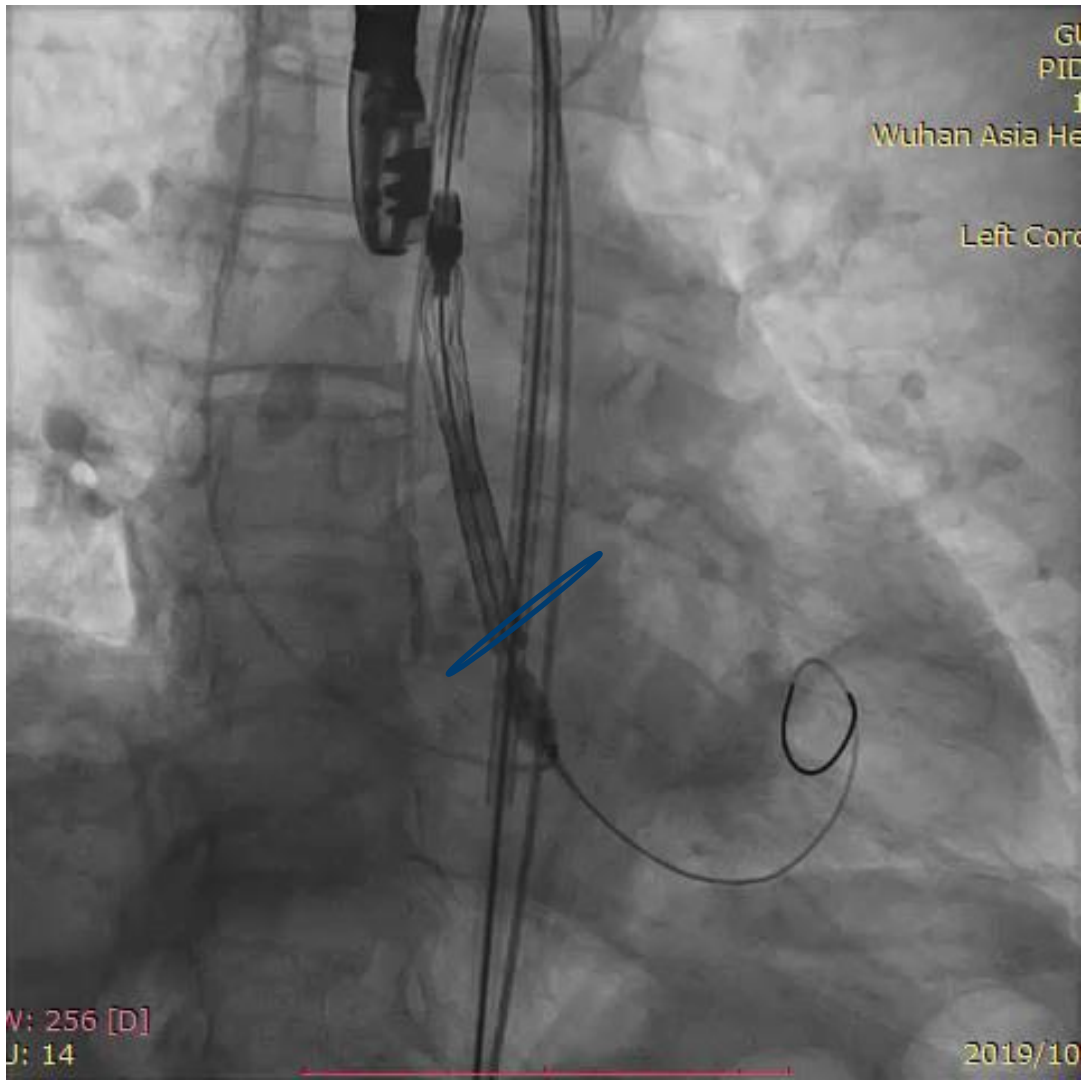
- ***If difficult to advance system, consider:***
- *Slightly pulling on guidewire to assist tracking across the aortic arch.*
- *Exchanging to a stiffer guidewire.*

Align annulus and marker band

- *Identify the ideal annular viewing plane to achieve coplanar imaging projection of native annulus and marker band, to see them as two straight lines on the fluoro image.*
- *Target implant depth : 0-6mm*

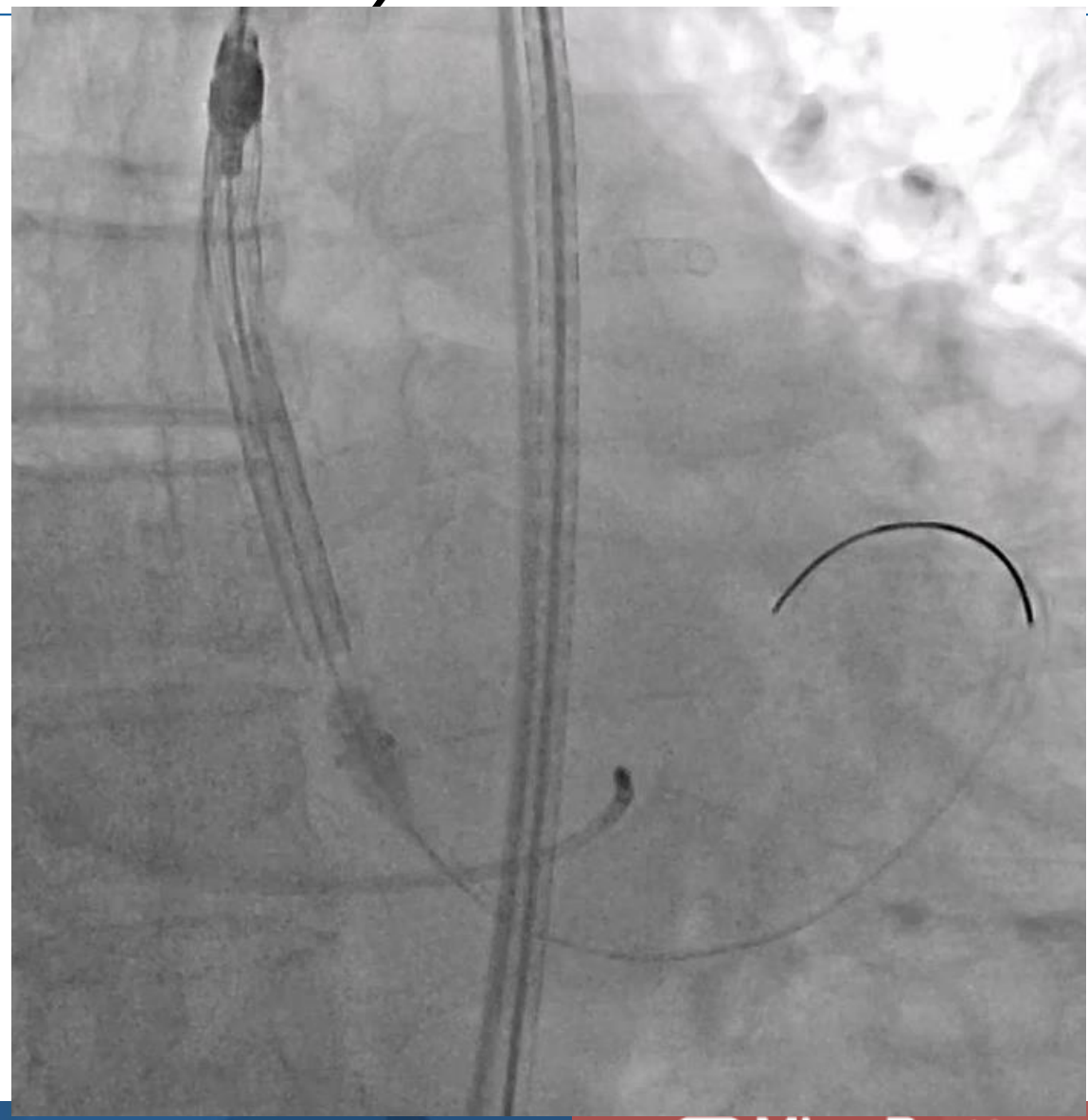






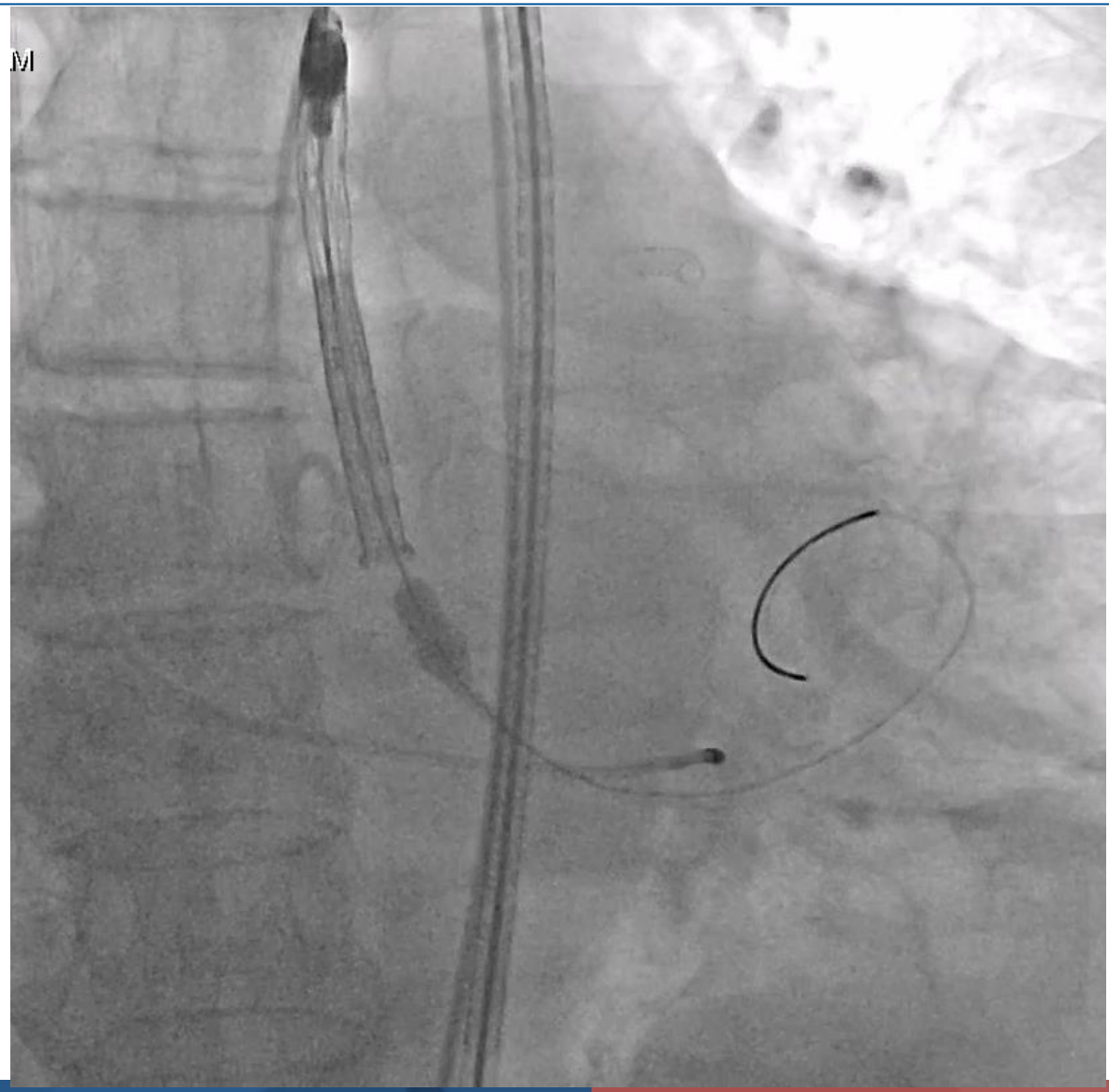
Deploy the valve(initial position)

- ***Click the backward button until the marker ring overlap with the first marker line(the bottom of the frame)***
- ***Do contrast injection again to assess position before the valve deploy***
- ***adjust the position if necessary***



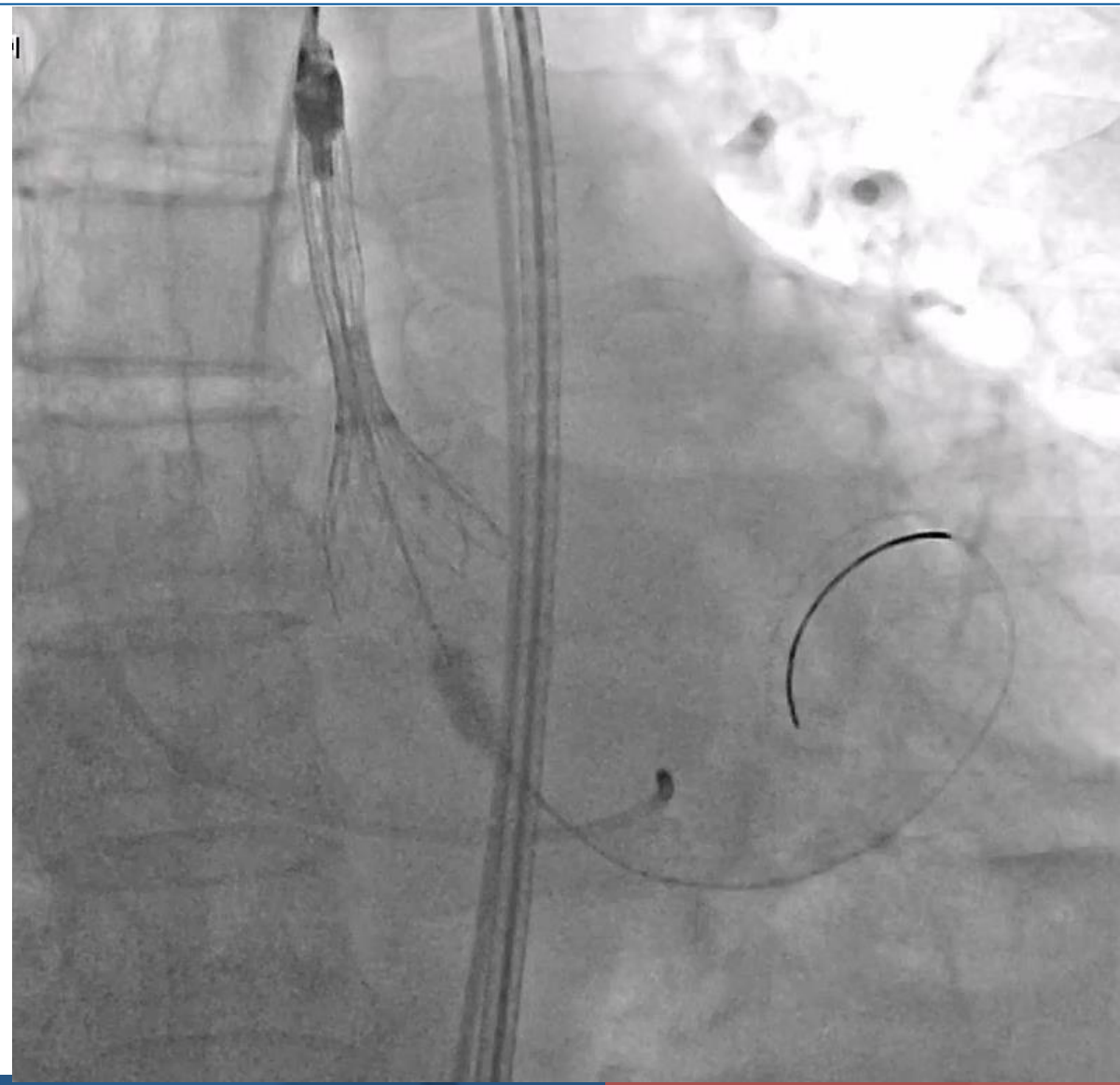
Deploy the valve (first 1/3)

- ***Deploy first 1/3 slowly***
- ***Consider controlled pacing at 90-140 bpm***
- ***The assistant hold the sheath and delivery system, the physician hold the handle and guidewire to support the valve position.***



Deploy the valve(1/3-2/3)

- ***Deploy middle 1/3 (normal speed)***
- *Assess position and confirm coronary perfusion to determine whether to deploy or recapture*
- *Find the right projection where the bottom of the stent is in a line to assess depth*



Deploy the valve(last 1/3)

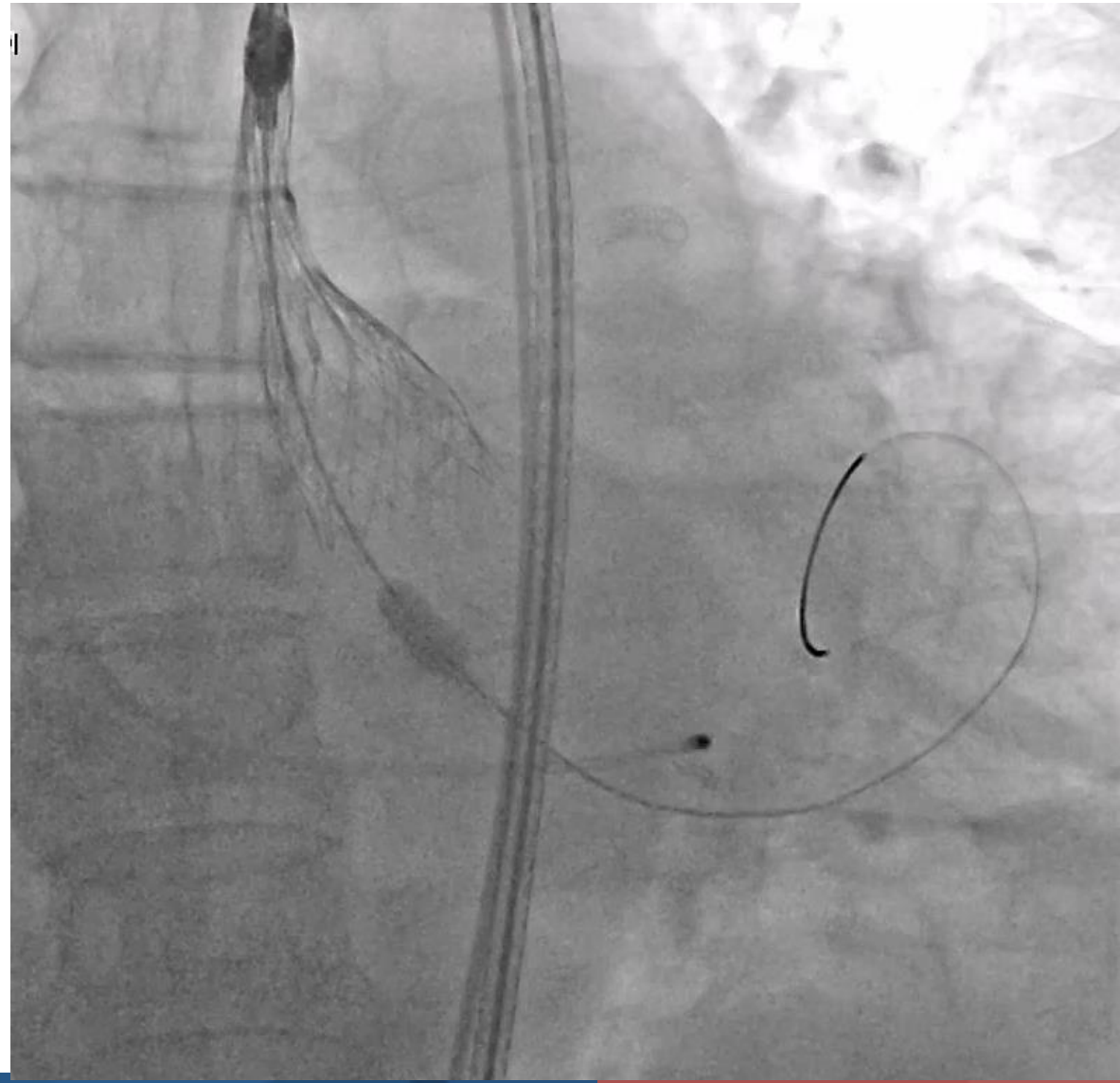
- ***Release tension in system& final release***
- *Slightly push the delivery system or pull the wire.*

- ***Deploy the last 1/3 of the valve***

- ***Confirm separation from paddles***
- *If a paddle does not separate from the paddle attachment, gently push or rotate the system until the valve releases.*

- ***Contrast injections to assess position***

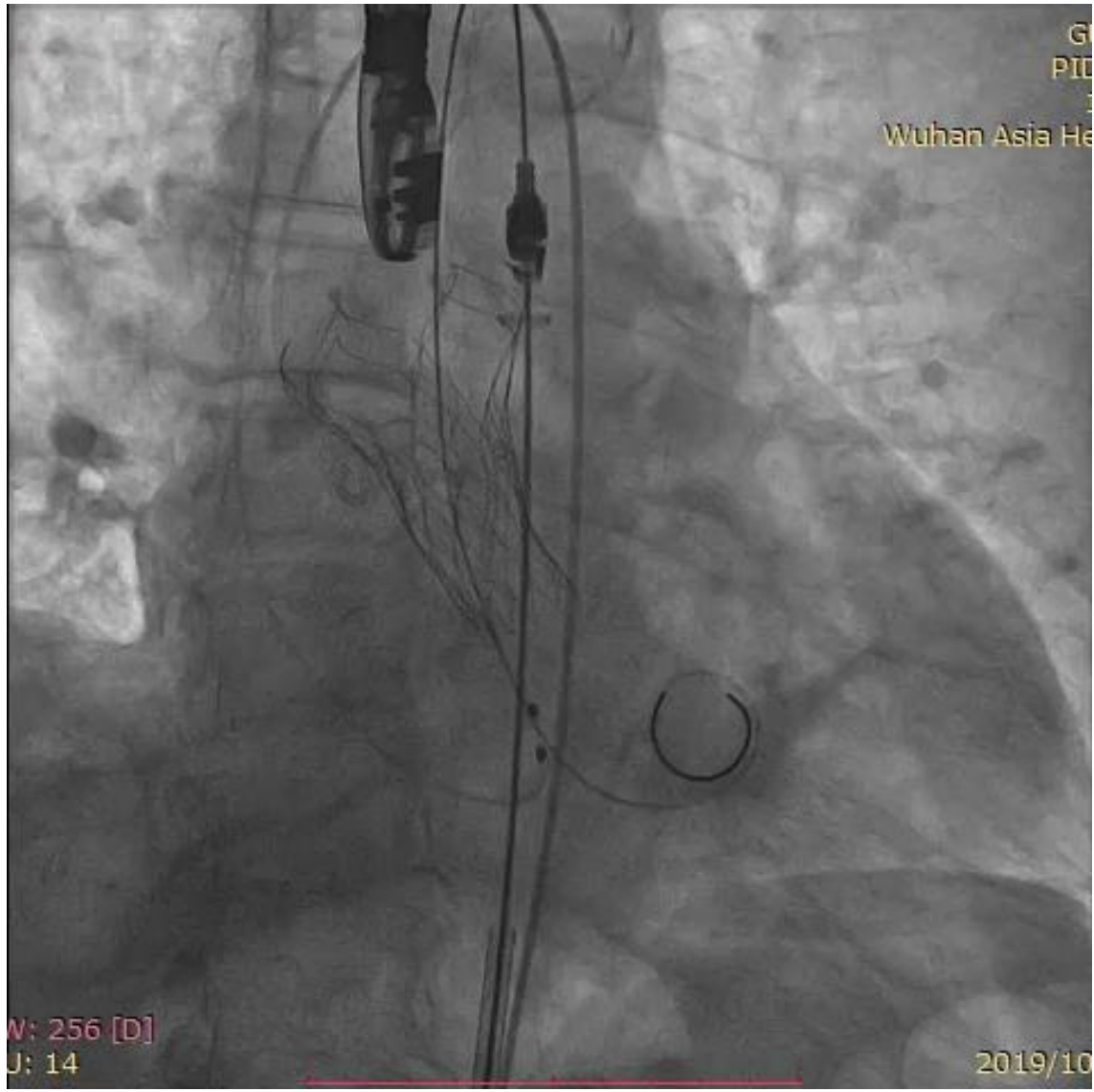
- ***Contrast injections to assess PVL***



Step 5 Withdraw delivery system

- ***Slowly withdraw the system into descending aorta.***

- ***Recapture nosecone and remove.***
- *For calcified descending aorta，pull the delivery system during recapture of the nosecone simultaneously might be safe.*



Assessing the result

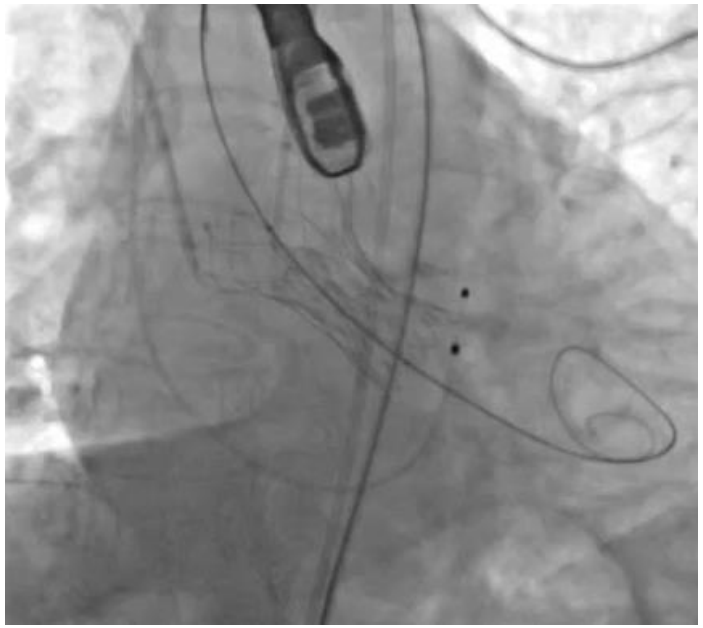
Angiography

Haemodynamics

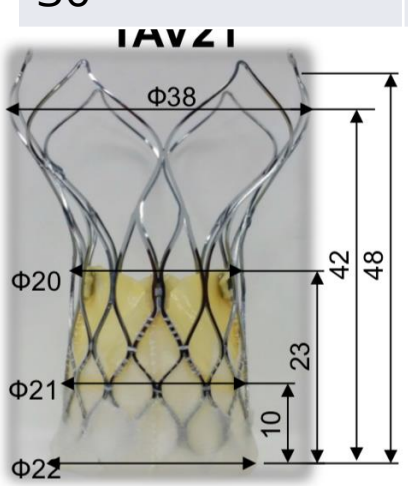
Echocardiography

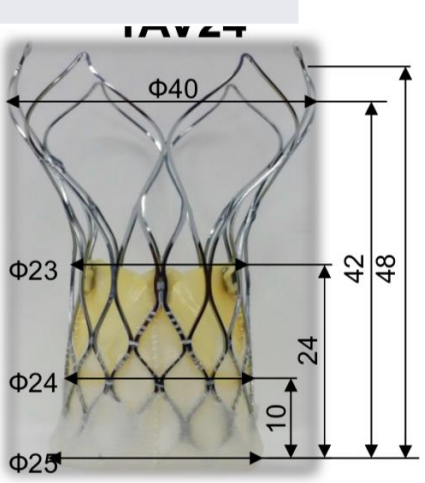
Post Dialation

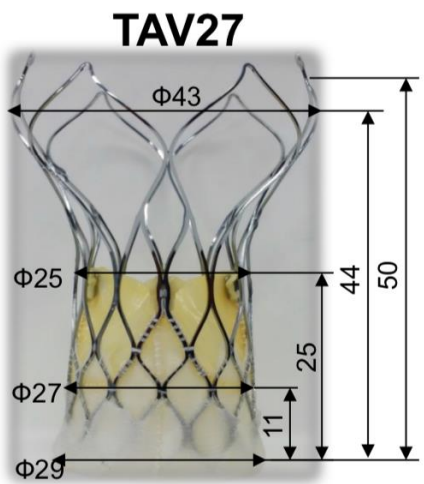
The balloon size should not exceed the waist of the bioprothesis,

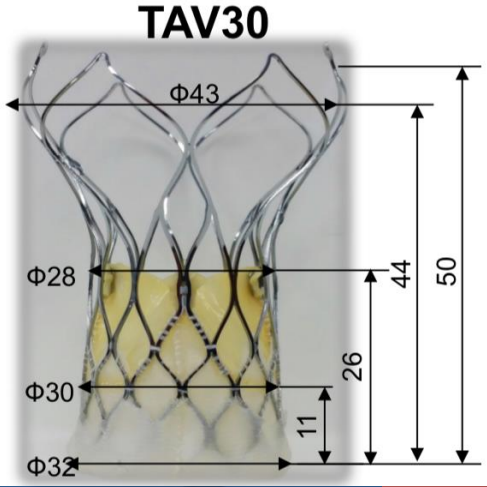


VitaFlow valve size	maximal Balloon size (mm)
21	20
24	23
27	25
30	28





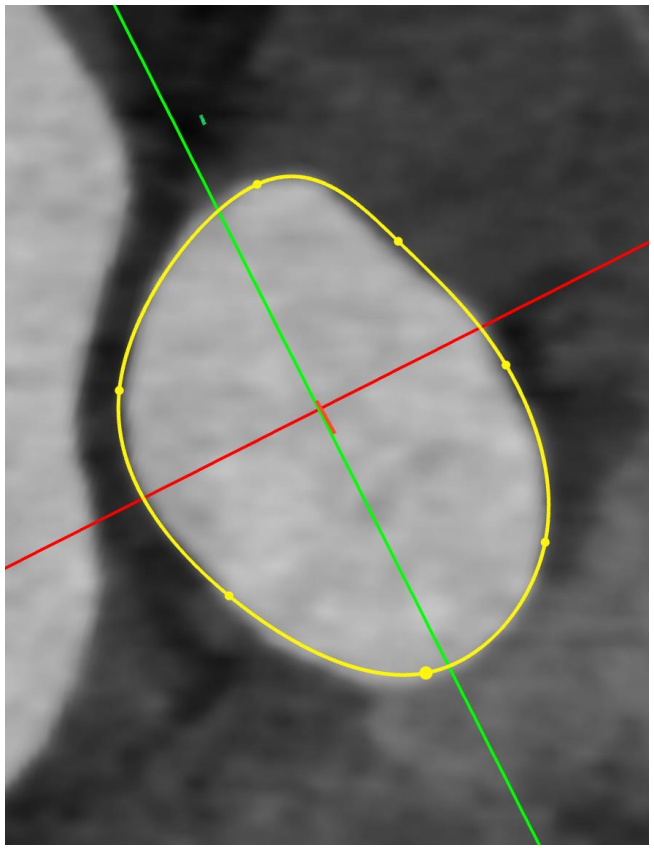


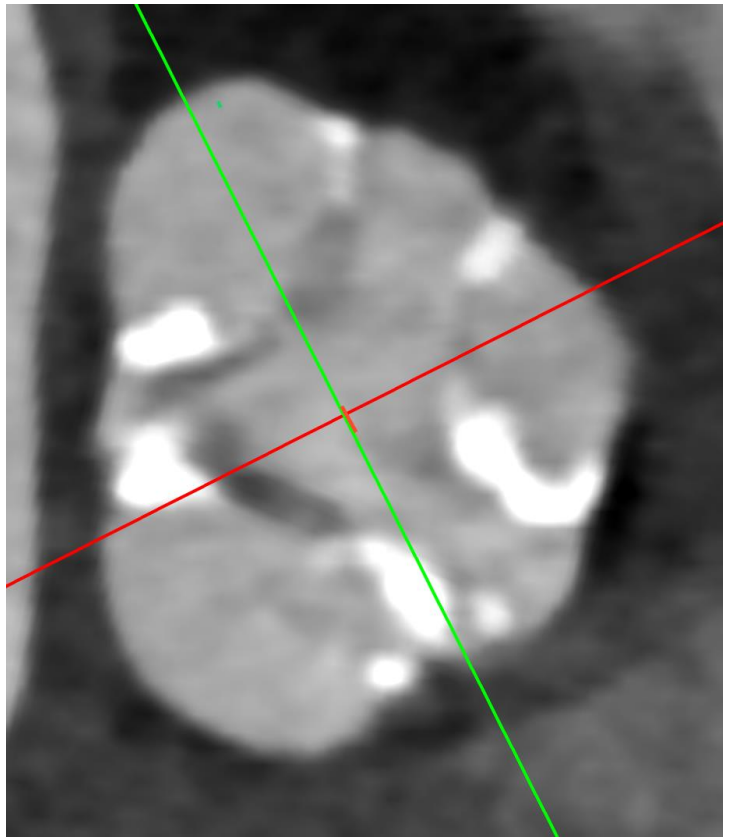


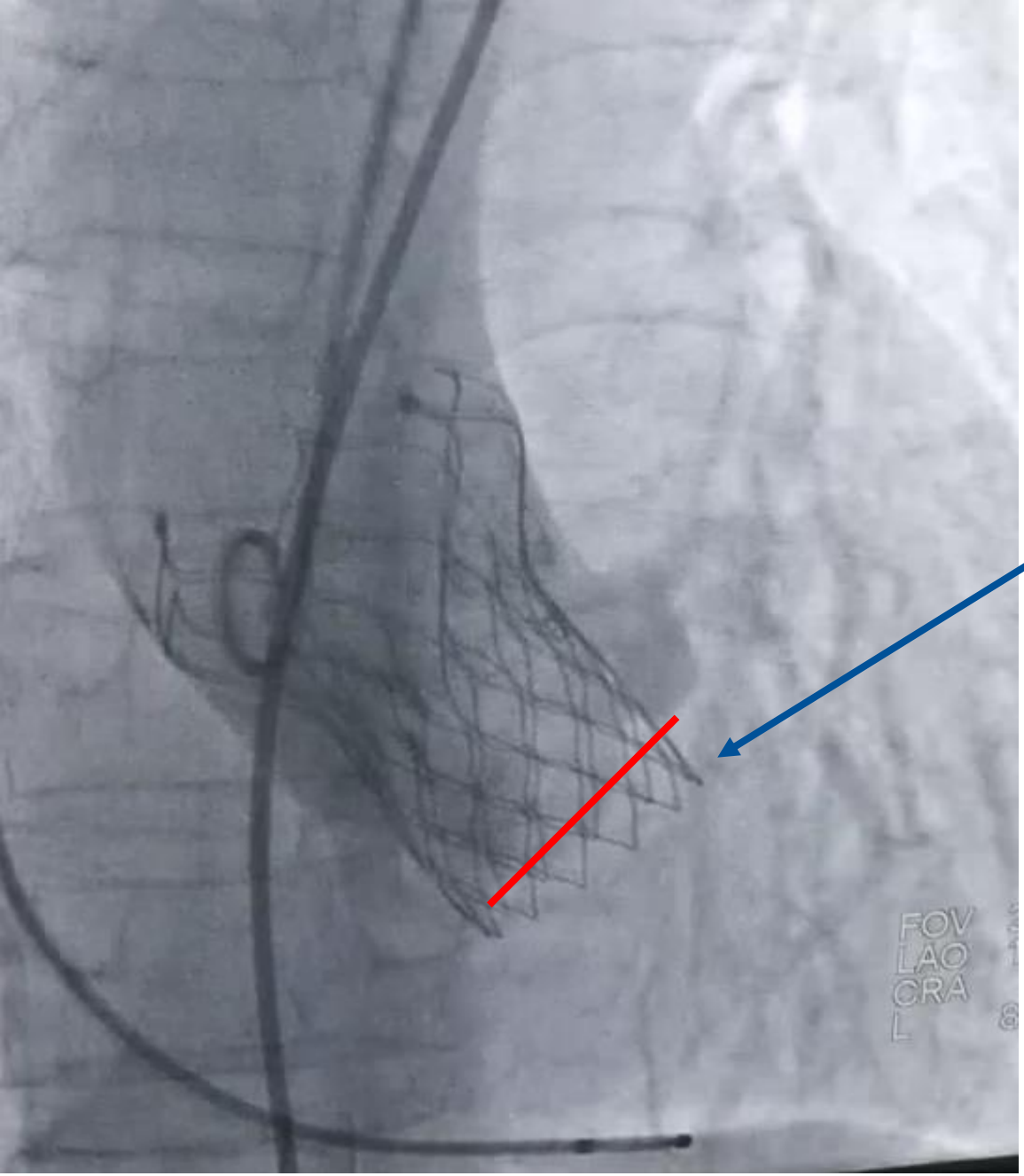
Individualized implant depth

Scenario 1: Calcified tricuspid valve

Typical calcified tricuspid valve stenosis, no commissure adhesion, no thickened le





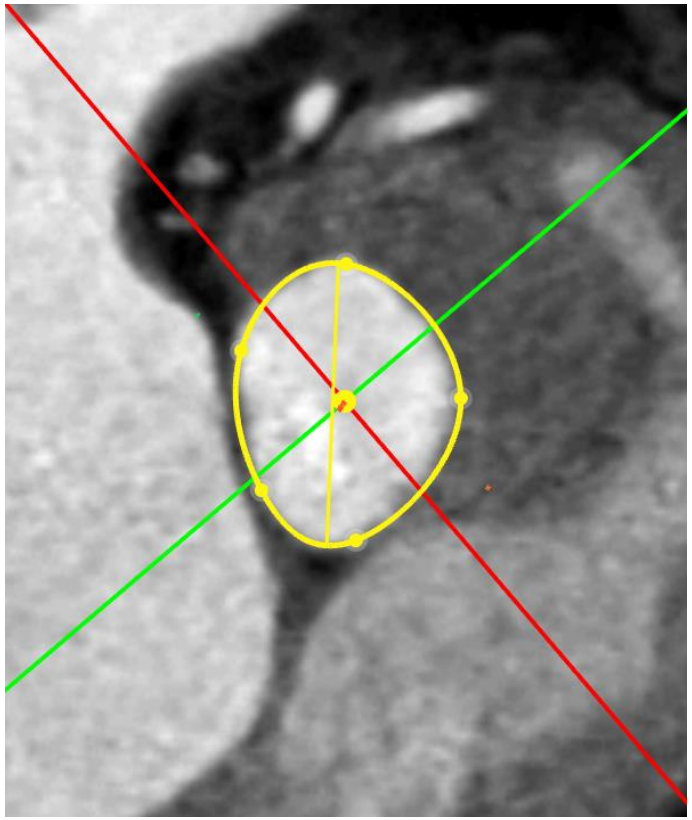


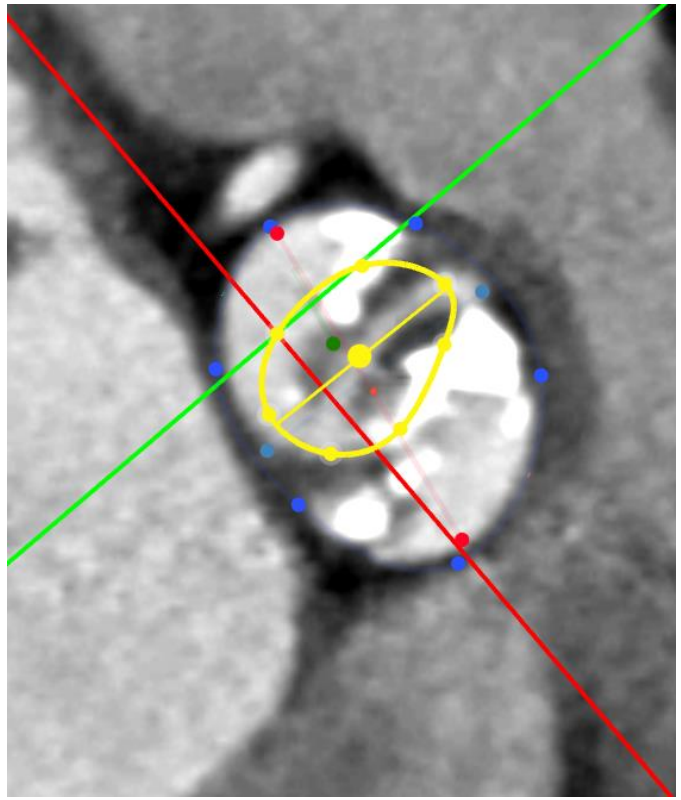
Standard depth:2~6mm

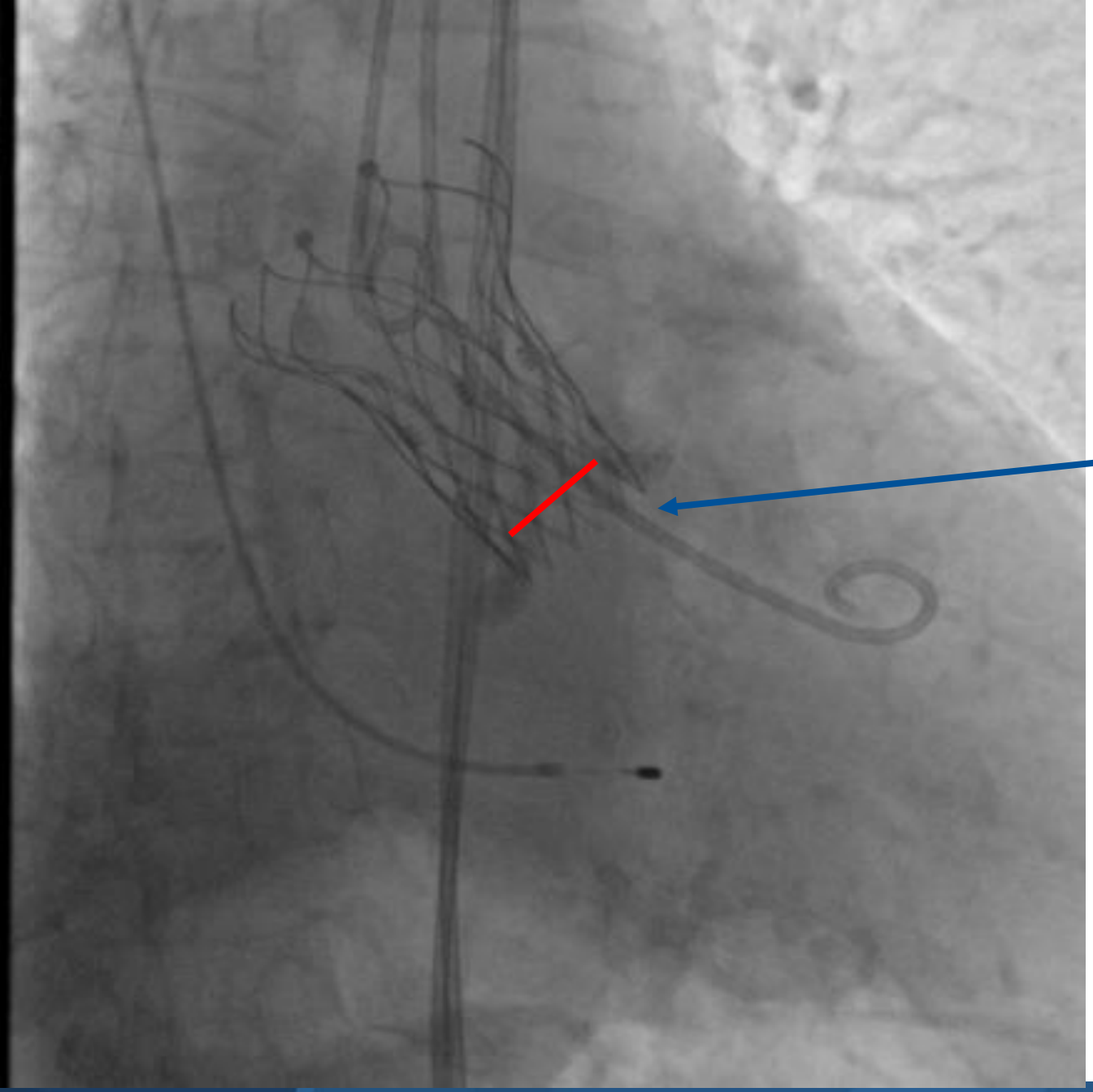
Landing zone: annulus

Scenario 2: Type 0 bicuspid valve

Type 0 bicuspid valve stenosis, severe calcified or thickened leaflet.
Most constrained area is 8mm above the annulus, the perimeter is 59mm(TAV21
The annulus perimeter is 78mm(TAV27).







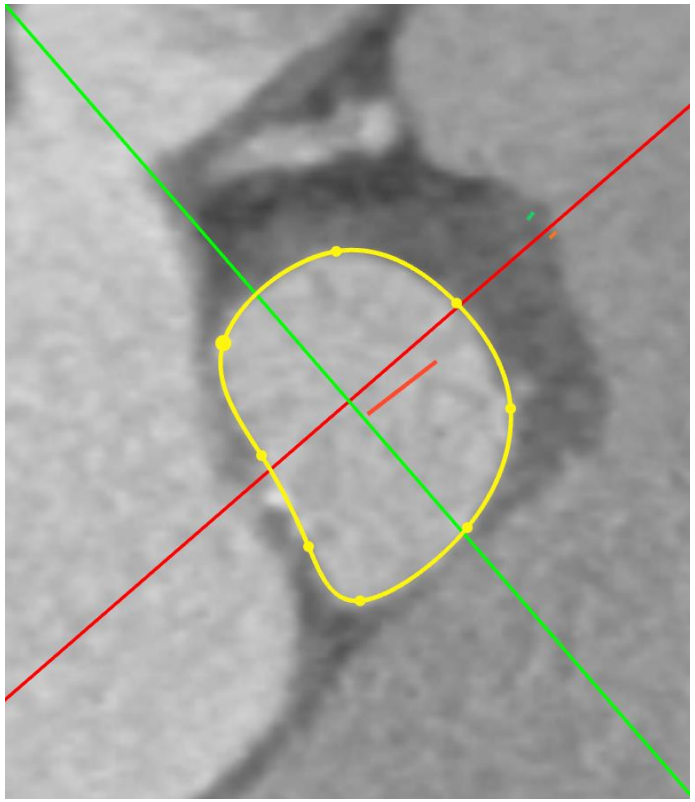
TAV 21

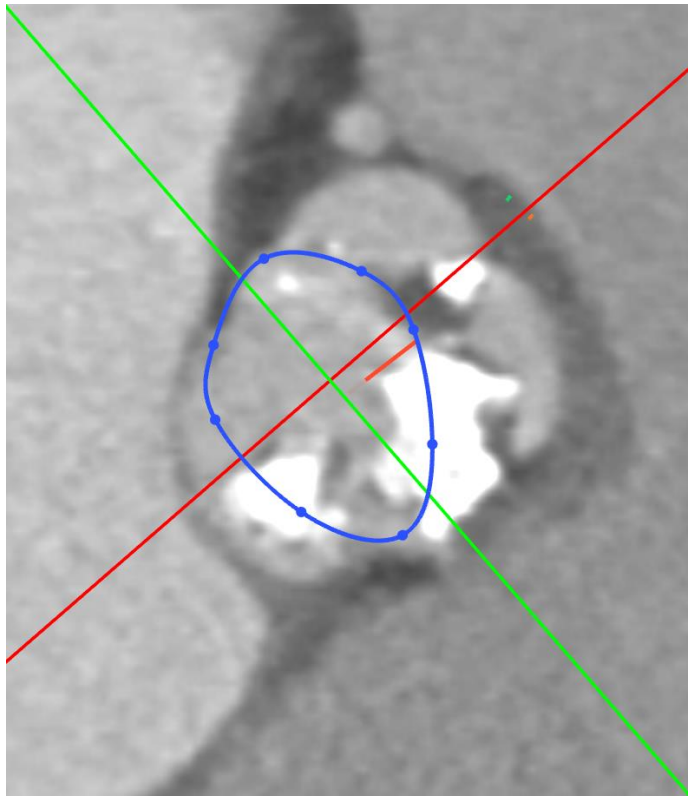
depth: -2 ~-4mm

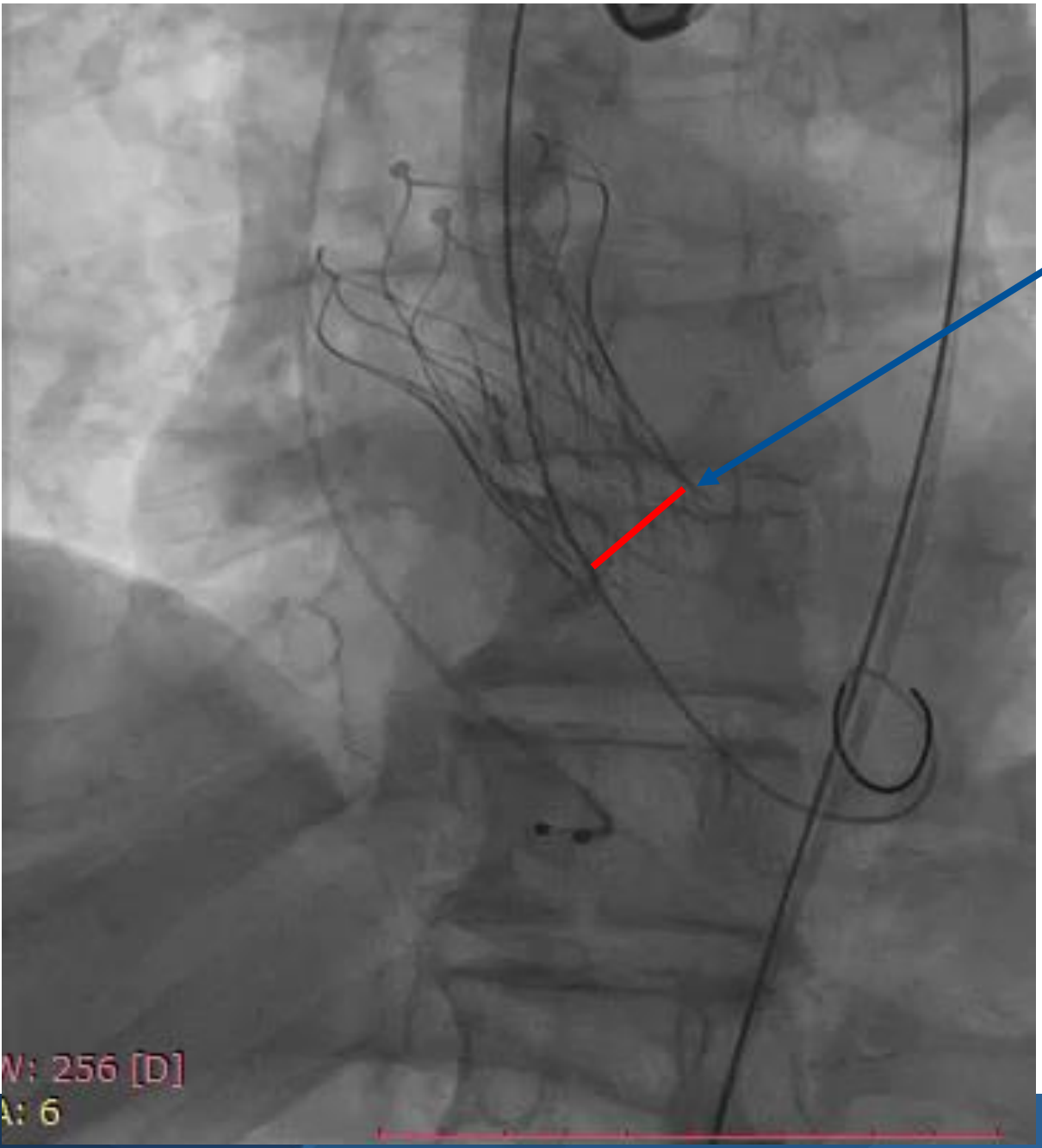
Landing zone: supra-annular(-8

Scenario 3: Type 1 bicuspid valve

Type 1 bicuspid valve, adhered left&right coronary cusp,
Most constrained area is 4mm above the annulus, perimeter is 66mm(TAV 24).
The annulus perimeter is 81mm(TAV27)







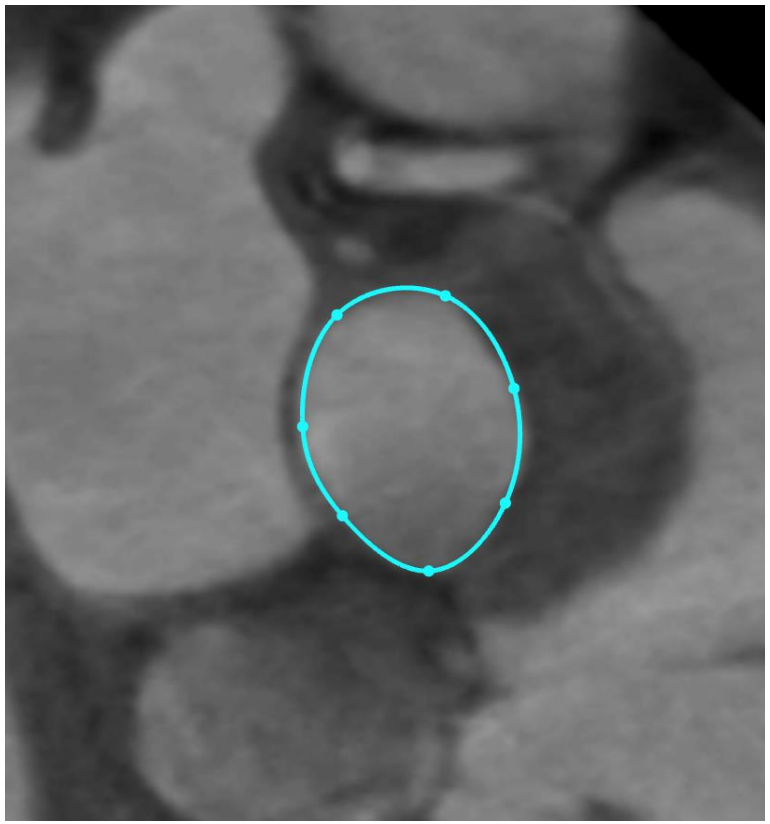
TAV 24

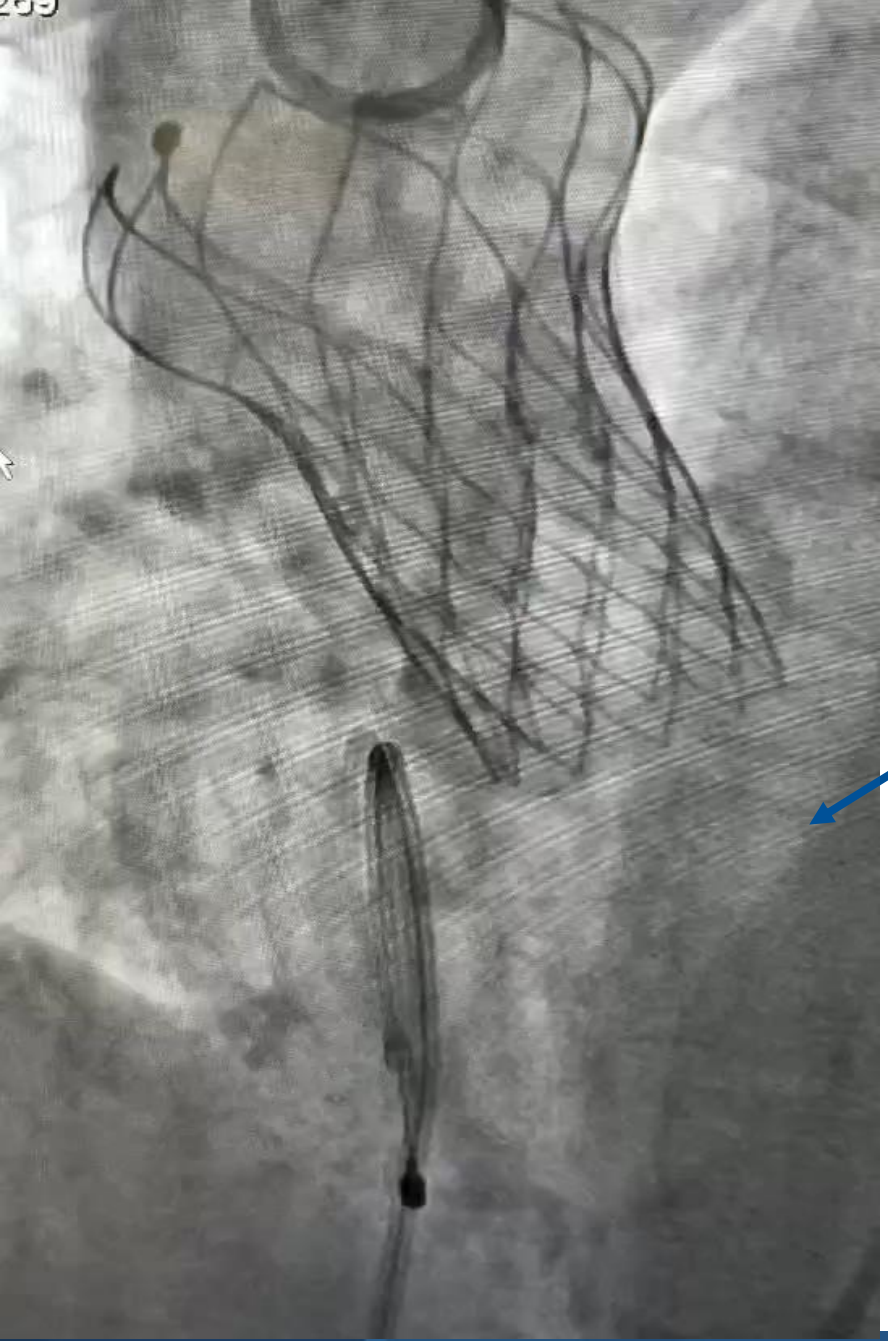
depth: 0~2mm

Landing zone: supra-annular(-4mm

Scenario 4: noncalcified Tricuspid valve

Noncalcified tricuspid stenosis ,thickened leaflets, usually rheumatic heart disease
Most constrained area is 6mm above the annulus, perimeter is 73mm(TAV 27).
The annulus perimeter is 83mm(TAV30).





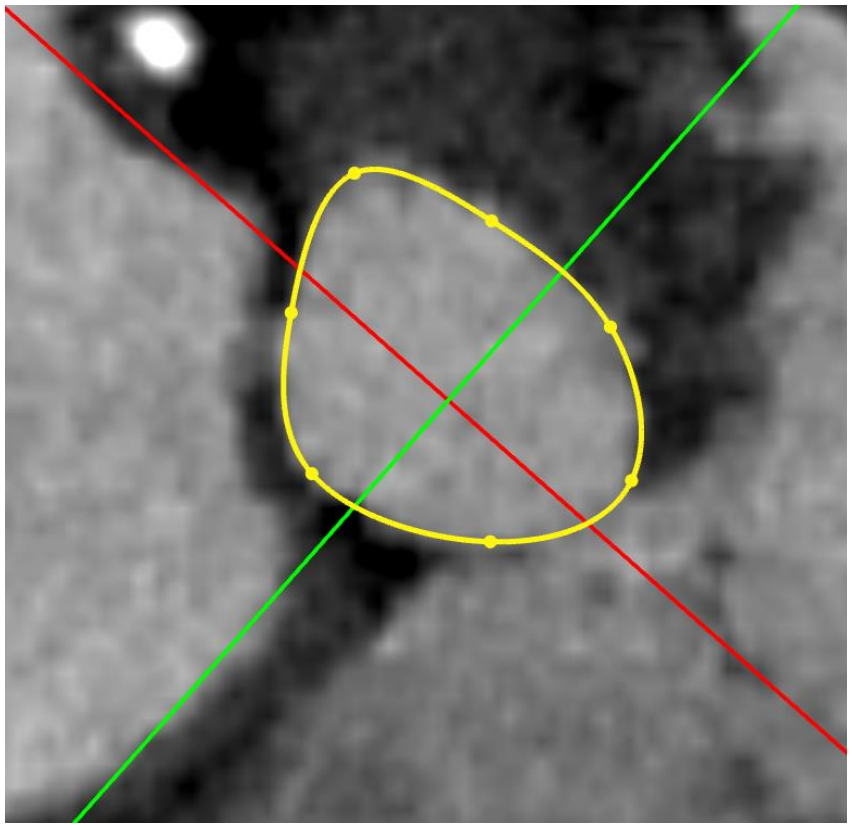
TAV 27

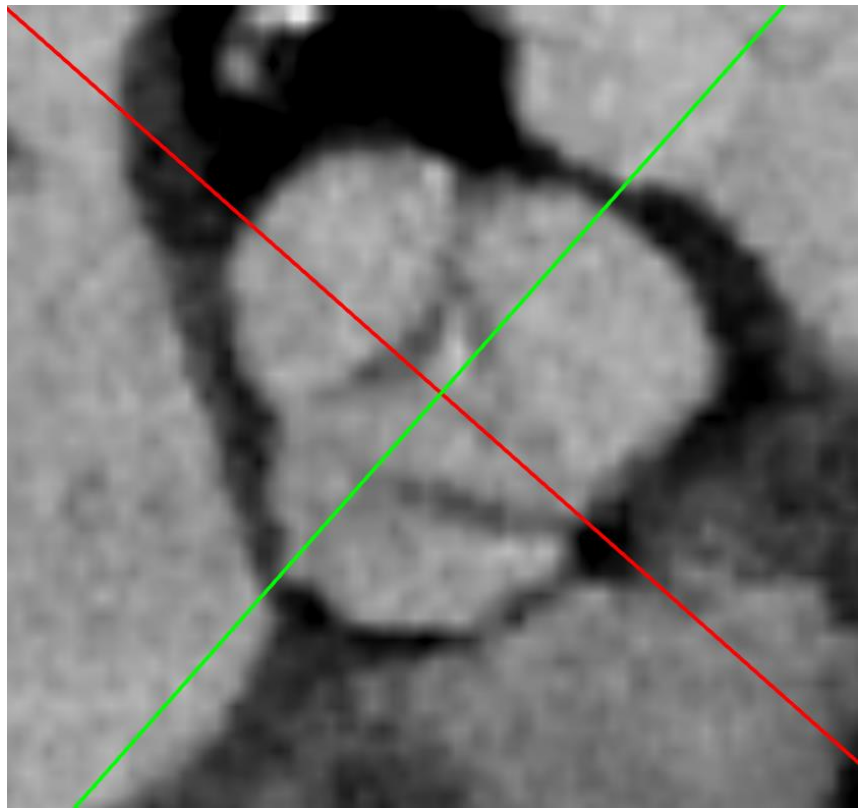
depth: -2~0mm

Landing zone: supra-annular(-6mm

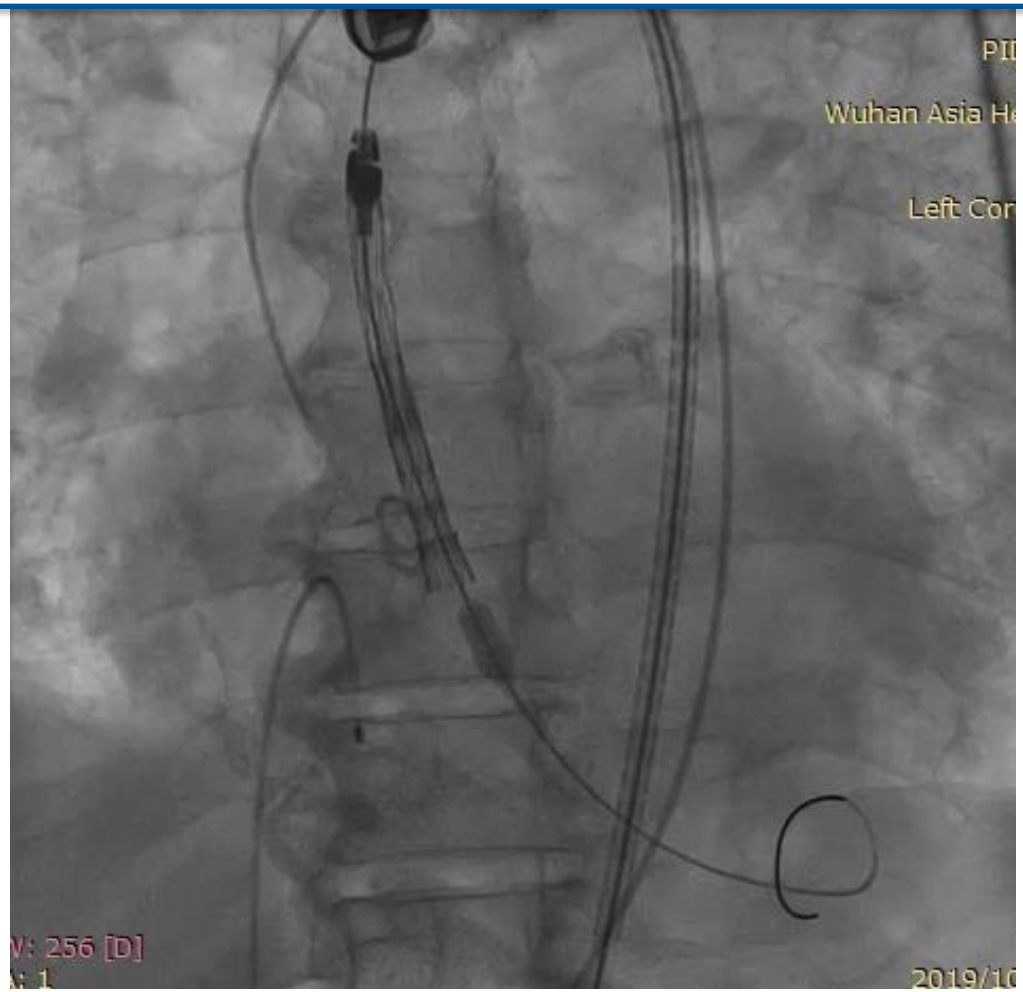
Scenario 5: pure aortic regurgitation

Pure AR，no calcification，no thickened leaflets.
The diameter of LVOT is approximate to the annulus.





Scenario 5: pure aortic regurgitation

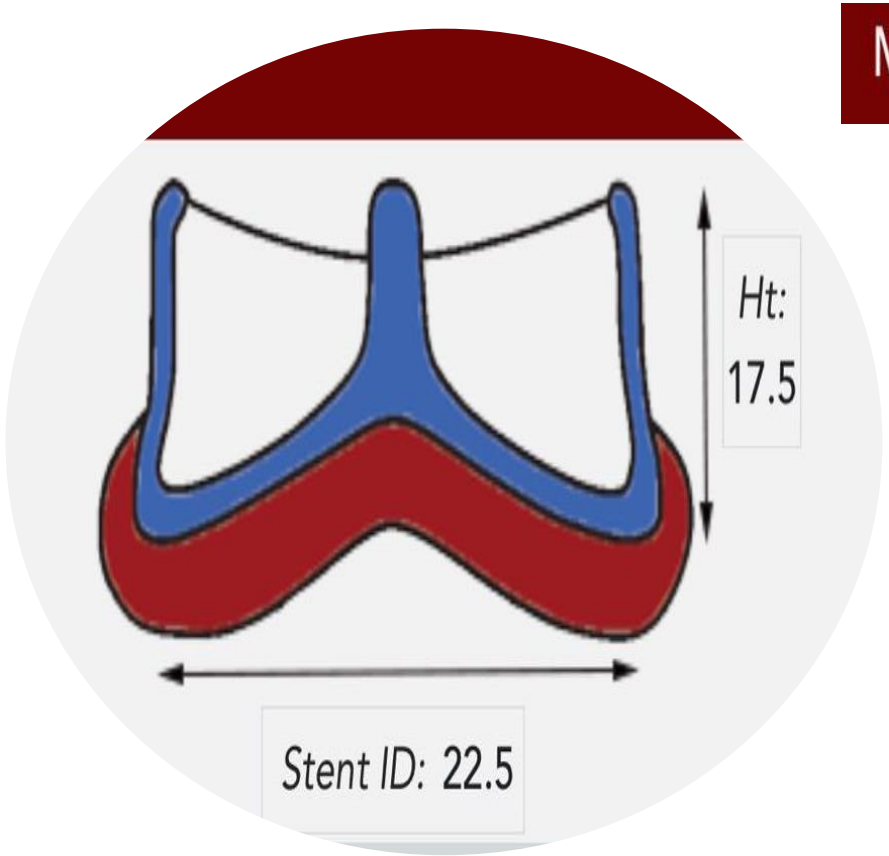


Initial implant depth：3-6mm

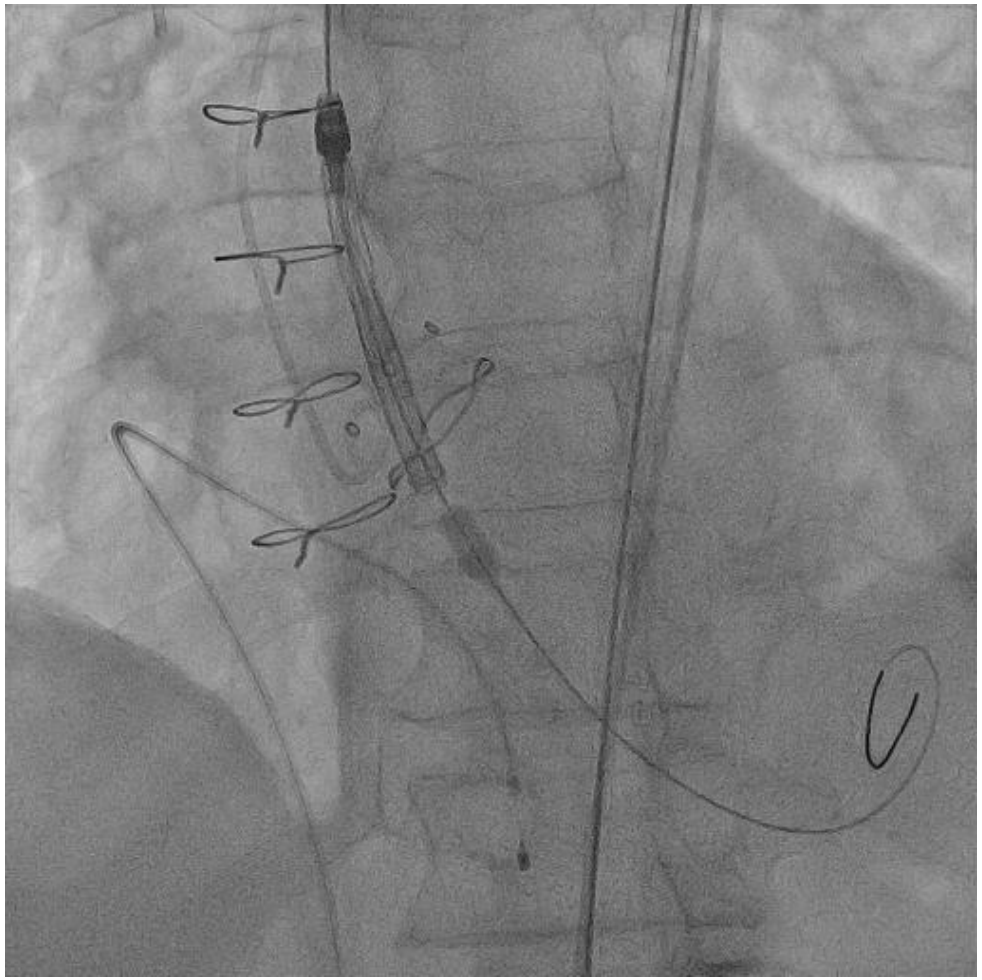
Final position：6mm

Scenario 6: TAV in SAV

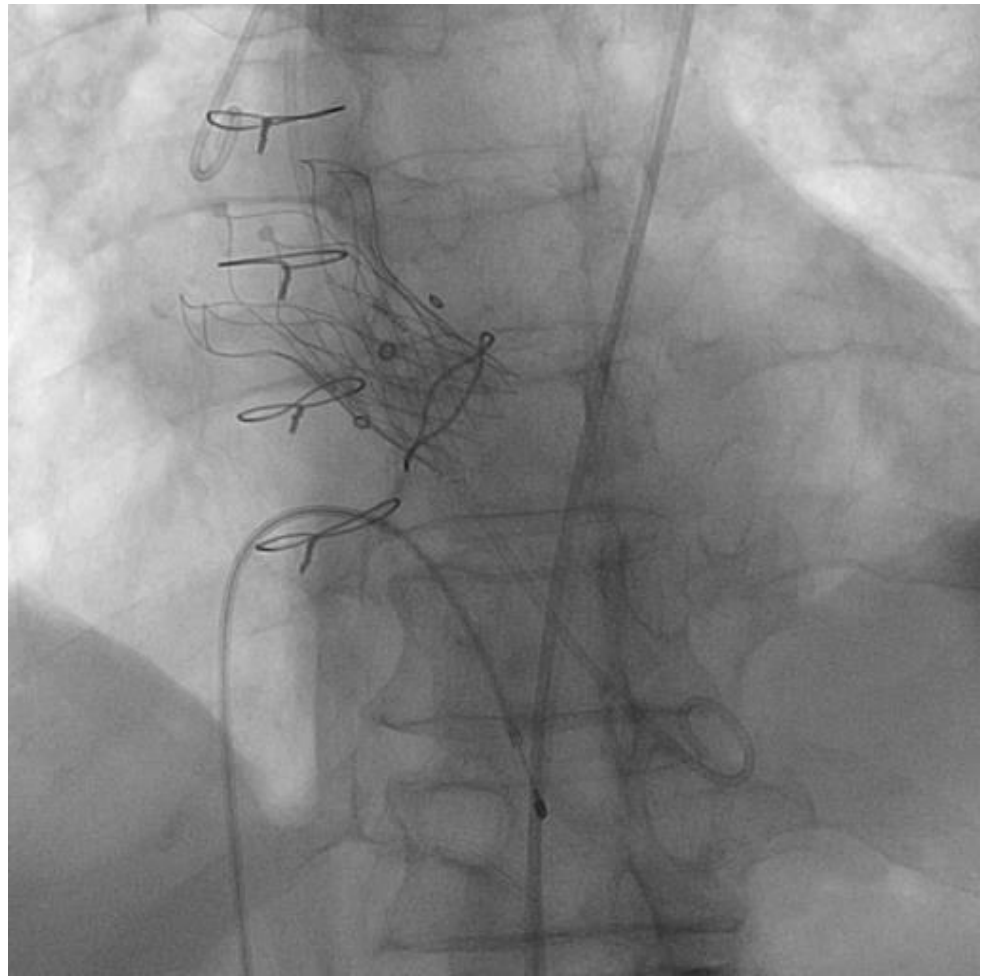
Parameters of Mosaic porcine bioprosthesis



Scenario 6: TAV in SAV

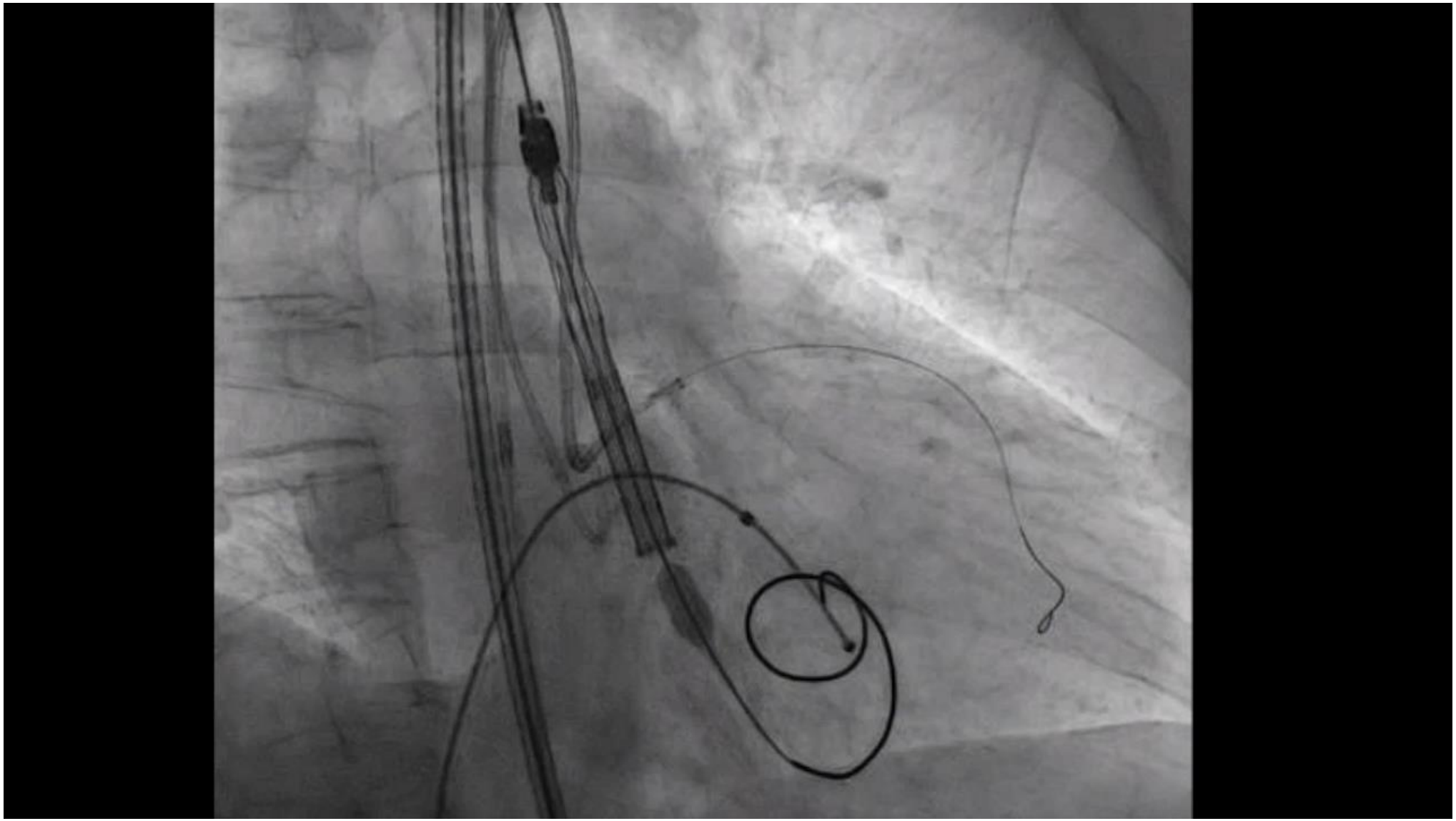


Initial implant depth：4-6mm

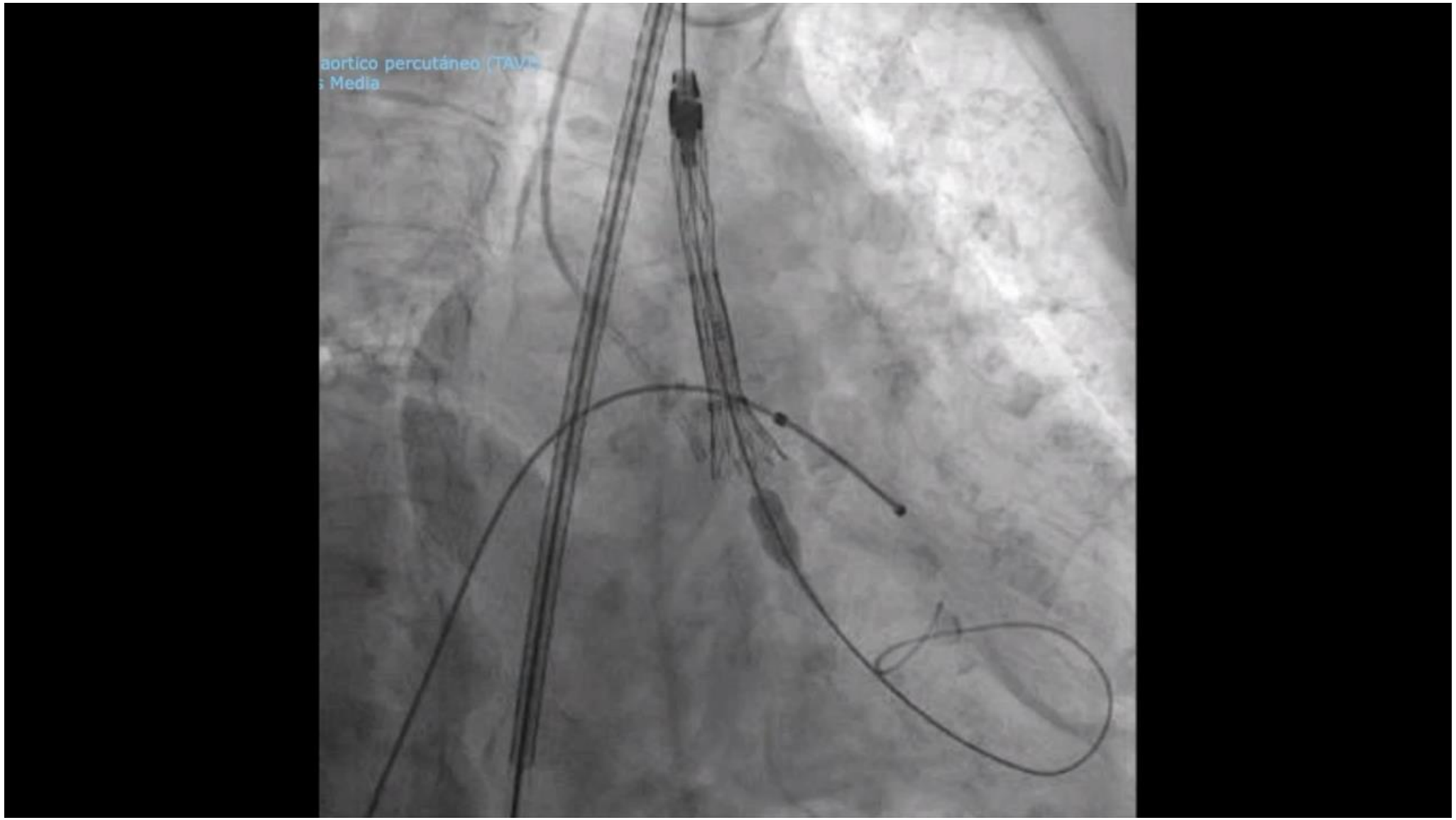


Final position：6mm

Clinical Case # – Sanatorio Mendez

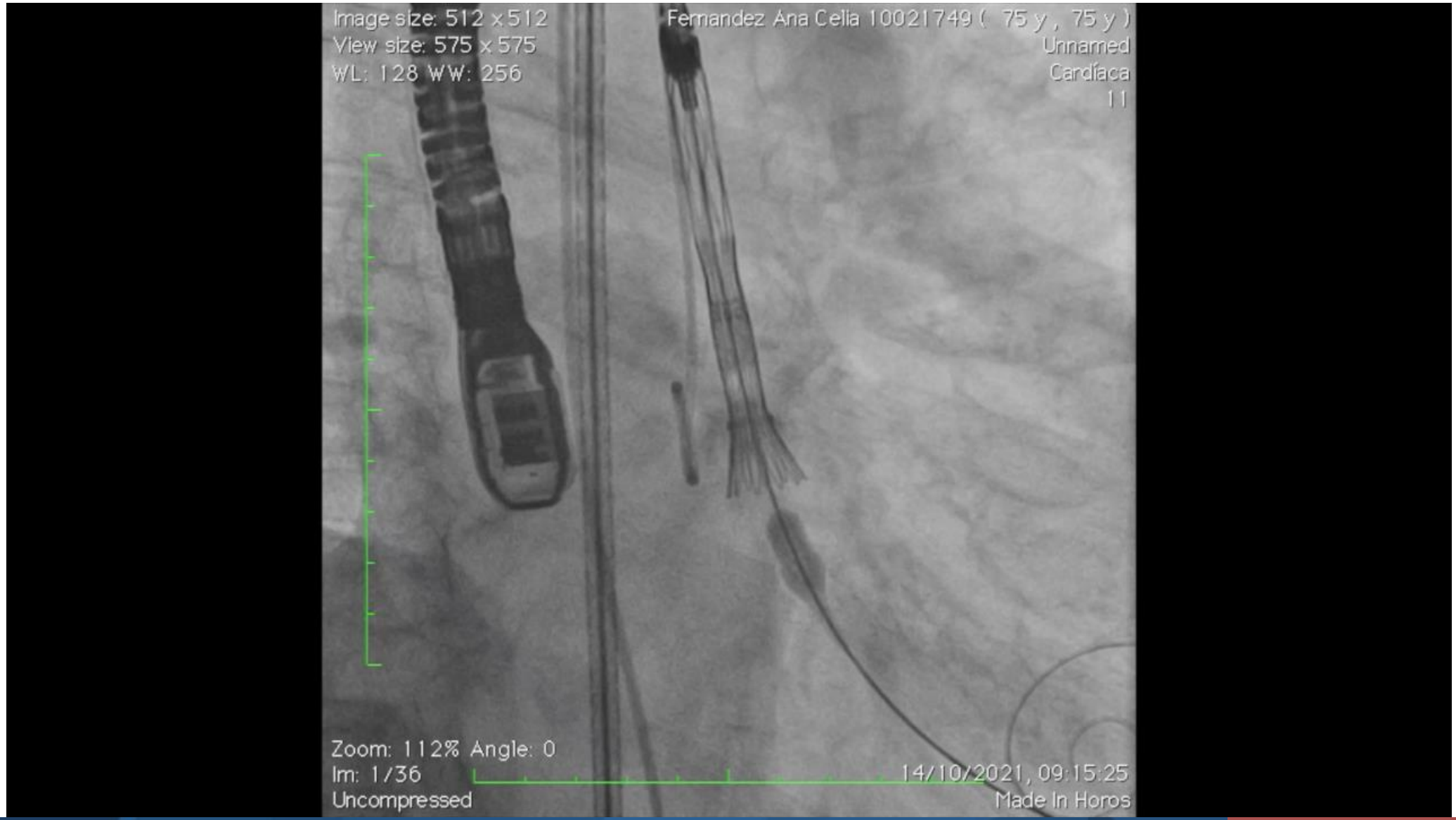


Clinical Case #– Sanatorio Mendez



Clinical Case# – Sanatorio Guemes

Clinical Case #– Sanatorio Boratti



Four year Clinical Outcomes of MicroPort Vitaflow Transcatheter Aortic Valve System in Patients with

- To evaluate the safety and effectiveness of VitaFlow® Valve and delivery system in symptomatic patients with severe calcific aortic stenosis, who are considered unsuitable for Surgical Valve Replacement.

- Prospective, multi-center, single-arm trial
- Enroll 110 patients
- All patients will be followed up at 30 days, 6 months, 12 months, and 2-5 years post TAVR*

- All cause mortality at 12 months

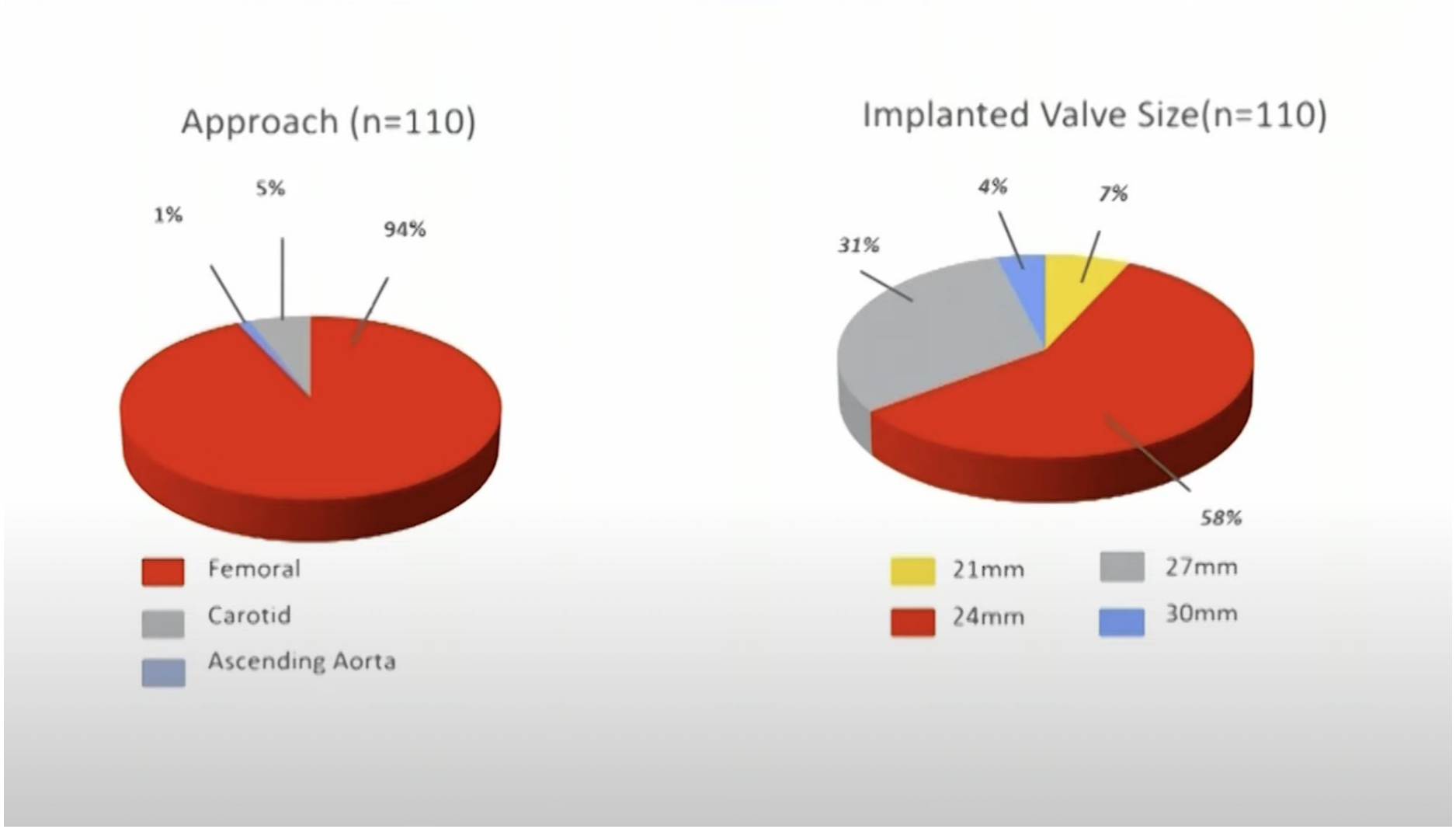
- Device success, Procedure success, Major Stroke, Valve performance, Improvement of heart function, MACCE, Improvement of life quality, etc.

*From year 2 to year 5, only all-cause mortality, cardiovascular mortality, stroke and other major complications are monitored

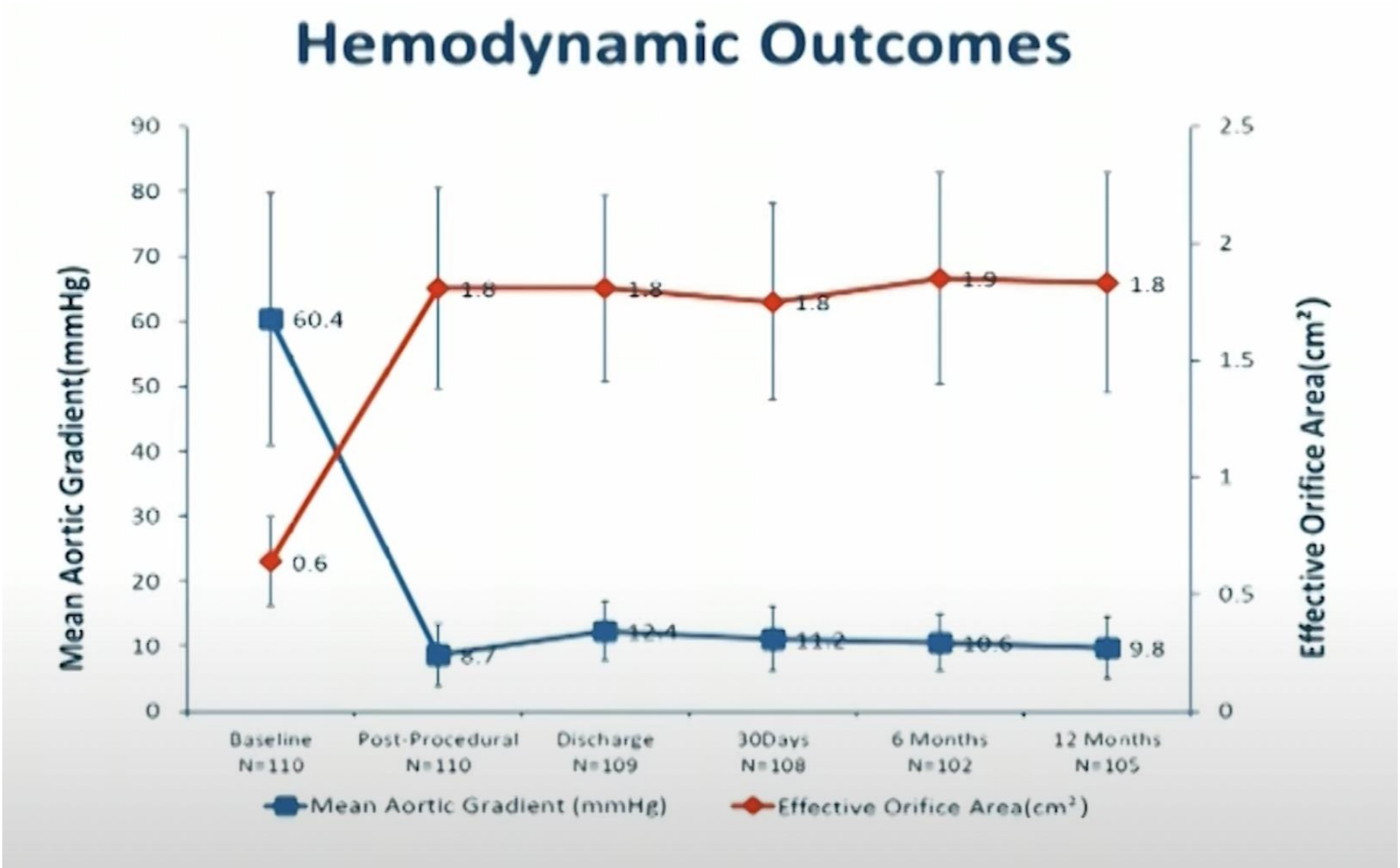
Baseline Characteristics

Characteristics	N=110	Characteristic	N=110
Mean Age – Year	77.73	COPD	24/110
Male Sex	60/110	Liver Disease	3/110
Mean STS Score	8.84	Renal Insufficiency	14/110
Coronary Artery Disease	62/110	Diabetes Mellitus	31/110
Hypertension	59/110	Cerebral Vascular Disease	24/110
Previous Myocardial Infarction	6/110	Bicuspid Aortic Valve Non-bicuspid Aortic Valve	42/110 68/110
Previous PCI	14/110	LVEF	57.22 ± 12.00
Peripheral Vascular Disease	45/110	Effective Orifice Area – cm^2	0.64 ± 0.19
Angina CCS Classes II-IV	20/110	Mean AV Gradient - mmHg	60.41 ± 19.40
Previous CABG	0/110		

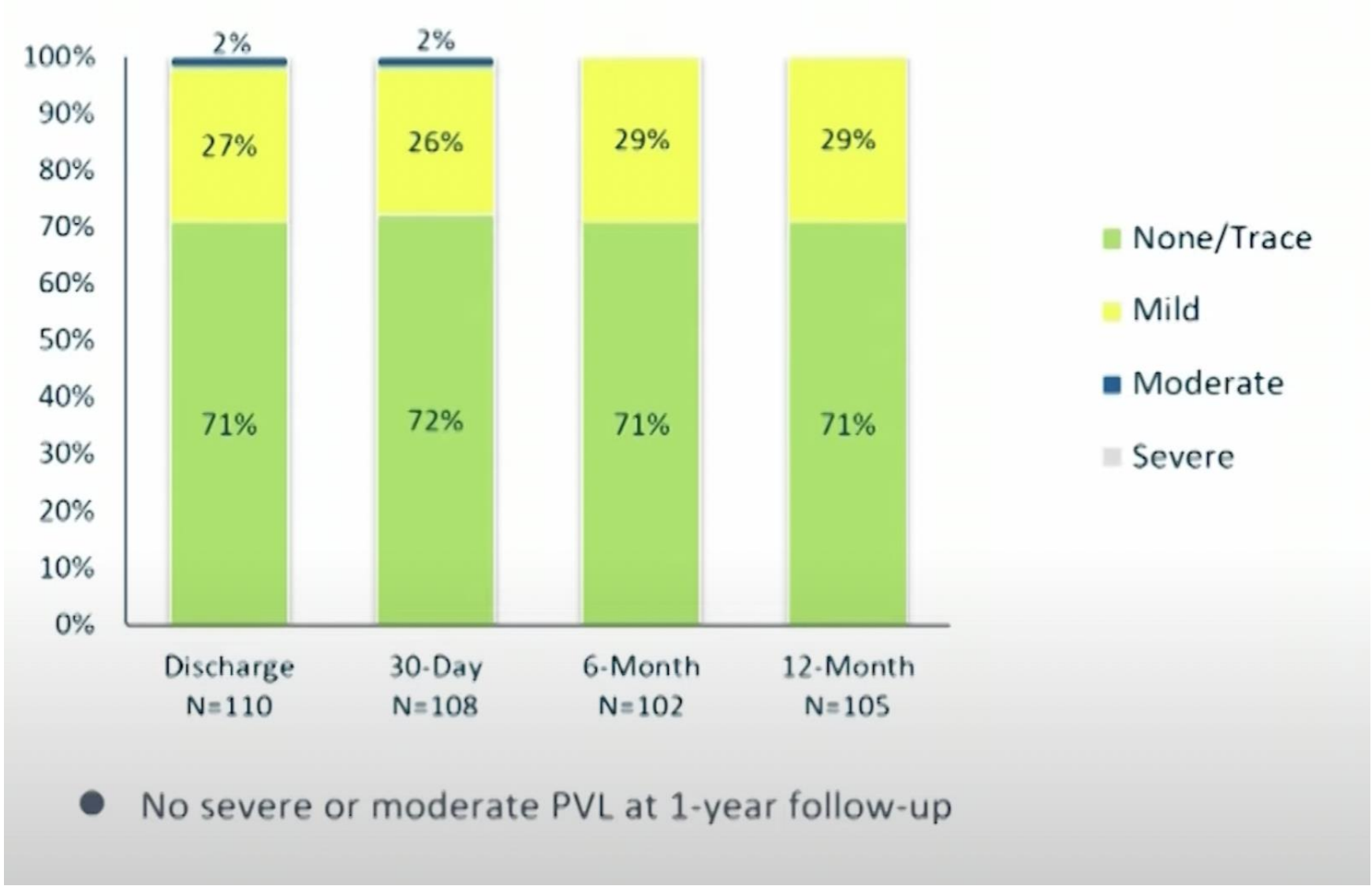
Approach & Valve Size



Hemodynamic Outcomes at 1 year Follow up



Para-valvular Leak at 1 year follow up



4 year Clinical Outcomes

Clinical Outcomes	Discharge, % N=110	30-Day, % N=110	6-Month,% N=110	1-Year, % N=110	2-Year, % N=110	3-year, % N=110	4-year, % N=110
All-cause Mortality	0.9% (1)	0.9% (1)	2.7% (3)	2.7% (3)	4.5%(5)	10.9%(12)	12.7%(14)
Cardiovascular Mortality	0.9% (1)	0.9% (1)	1.8% (2)	1.8% (2)	2.7%(3)	7.2%(8)	7.2%(8)
All Stroke (Major & Minor)	1.8% (2)	2.7% (3)	4.5% (5)	4.5% (5)	7.3%(8)	11.8%(13)	12.7%(14)
Major Stroke	0.0%(0)	0.0%(0)	0.0%(0)	0.0%(0)	0.0%(0)	1.8%(2)	1.8%(2)
Major Vascular Complication	1.8% (2)	1.8% (2)	2.7% (3)	2.7% (3)	2.7% (3)	2.7%(3)	2.7%(3)
New Pacemaker Implantation	15.5% (17)*	16.4% (18)*	19.1% (21)*	19.1% (21)*	19.1% (21)*	20.0%(22)*	20.0%(22)*

* 5.5% (6) patients with I° AVB

Summary

Conclusions:

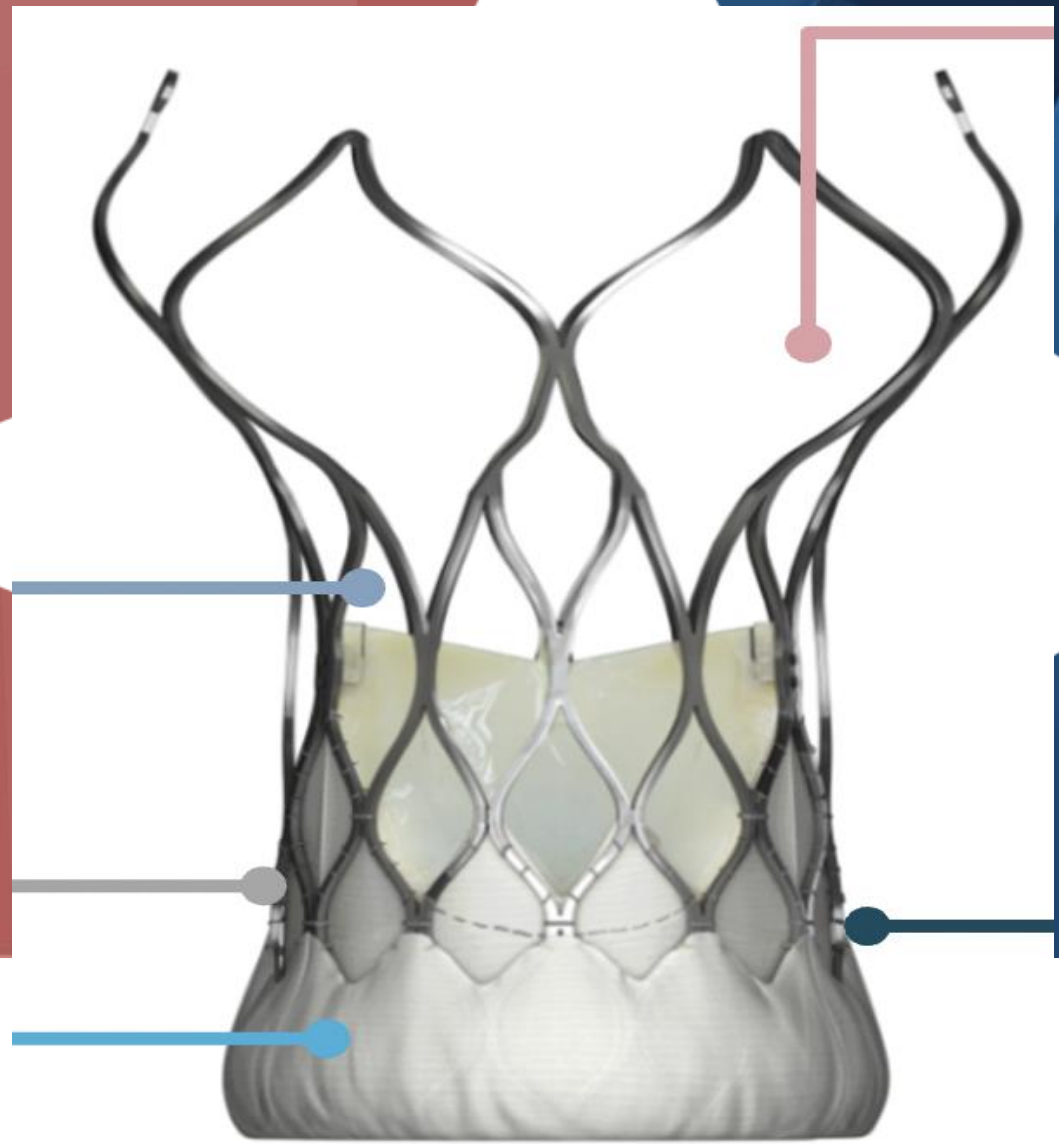
- Good hemodynamic results at 1-year follow-up
- Low all-cause mortality and cardiovascular mortality rate at 1-year follow-up
- All-cause mortality rate at 4-year follow-up, 12.7%
- Cardiovascular mortality rate at 4-year follow-up, 7.2%

The 4-year clinical outcomes support the safety and efficacy of MicroPort VitaFlow® in the treatment of patients with severe aortic stenosis.

Conclusion

- *Unique motorized delivery system to provide continuous and stable deployment.*
- *As an advice: use usual temporary pacemaker.*
- *Cusp Overlap Technique then left oblique.*
- *Design for low risk of perivalvular leak and complications.*
- *Enough Radial force.(bicuspid valve-extreme calcification*
- *Easy Coronary access.*
- *Valve with treatment against Calcification at follow up.*
- *So far ,Excellent Local results.*
- *Long term follow up 4 years with clinical outcome.*
- *Next generation available on February in Argentina.*

MicroPort® CardioFlow



Thanks for your attention!

VitaFlow™