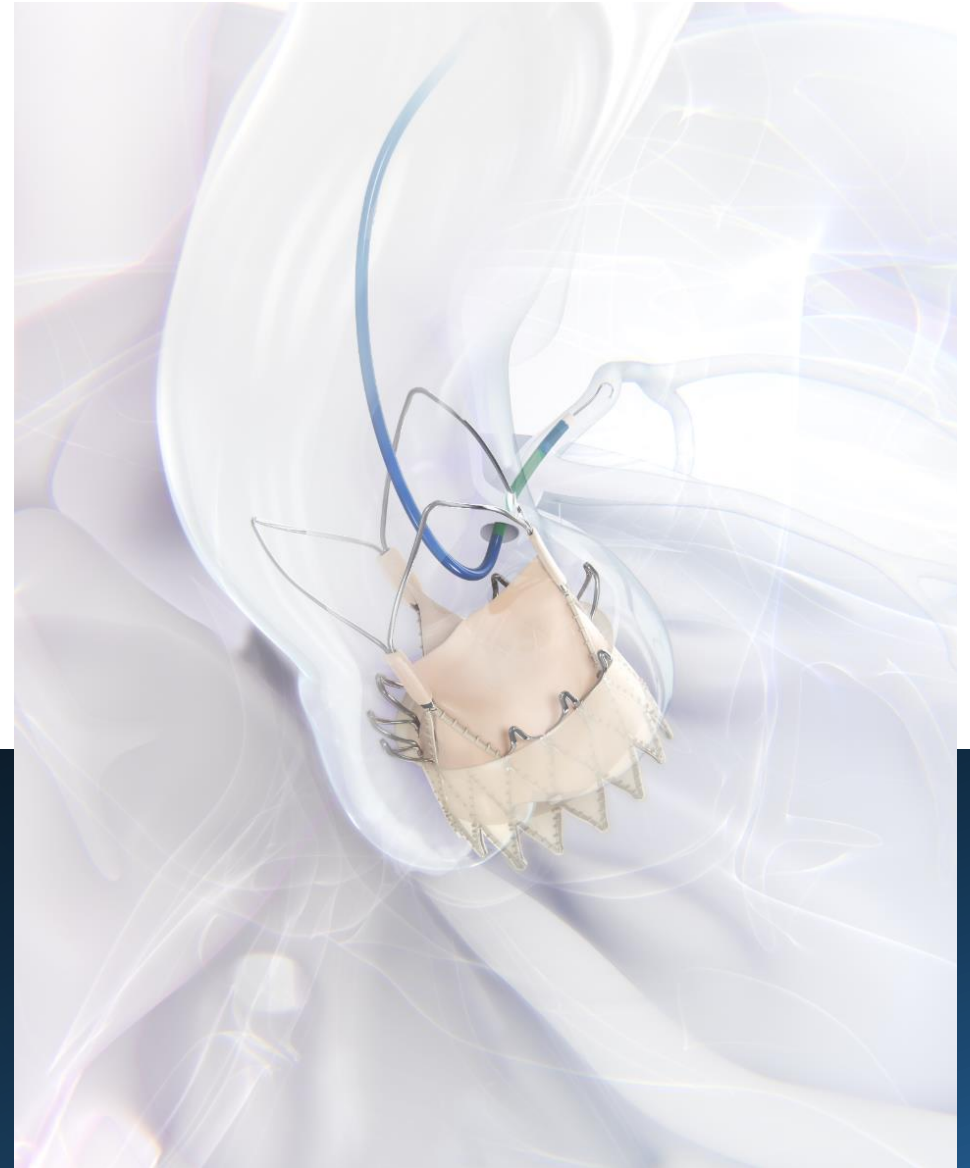


Mastering Commissural Alignment with ACURATE neo2: Significance and Techniques

Hyungdon Kook, MD, PhD
Hanyang University Seoul Hospital,
Seoul, Korea



Disclosure

Speaker's name : Hyungdon Kook

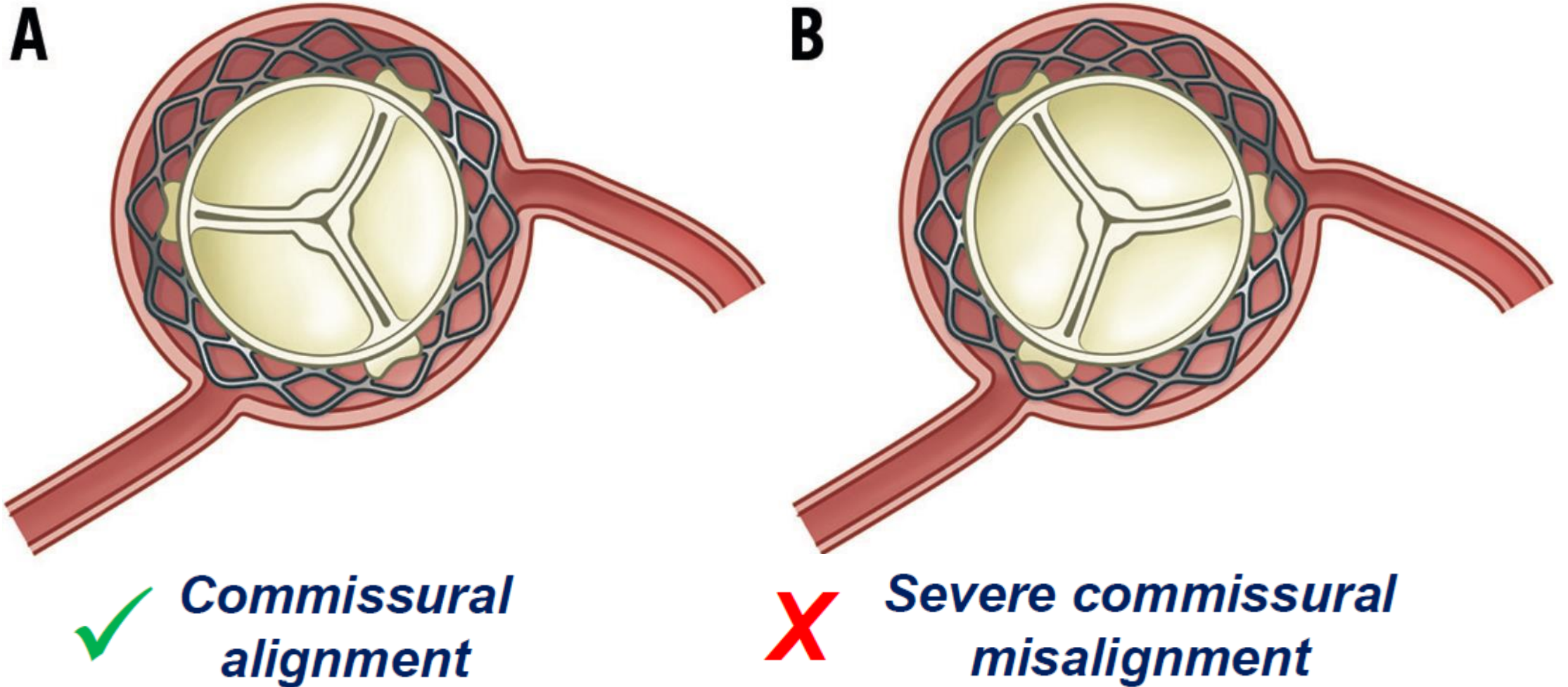
Receipt of honoraria or consultation fees:

- Boston Scientific
- Genoss

Regional TAVR proctor of:

- Edwards Lifesciences
- Medtronic
- Boston Scientific

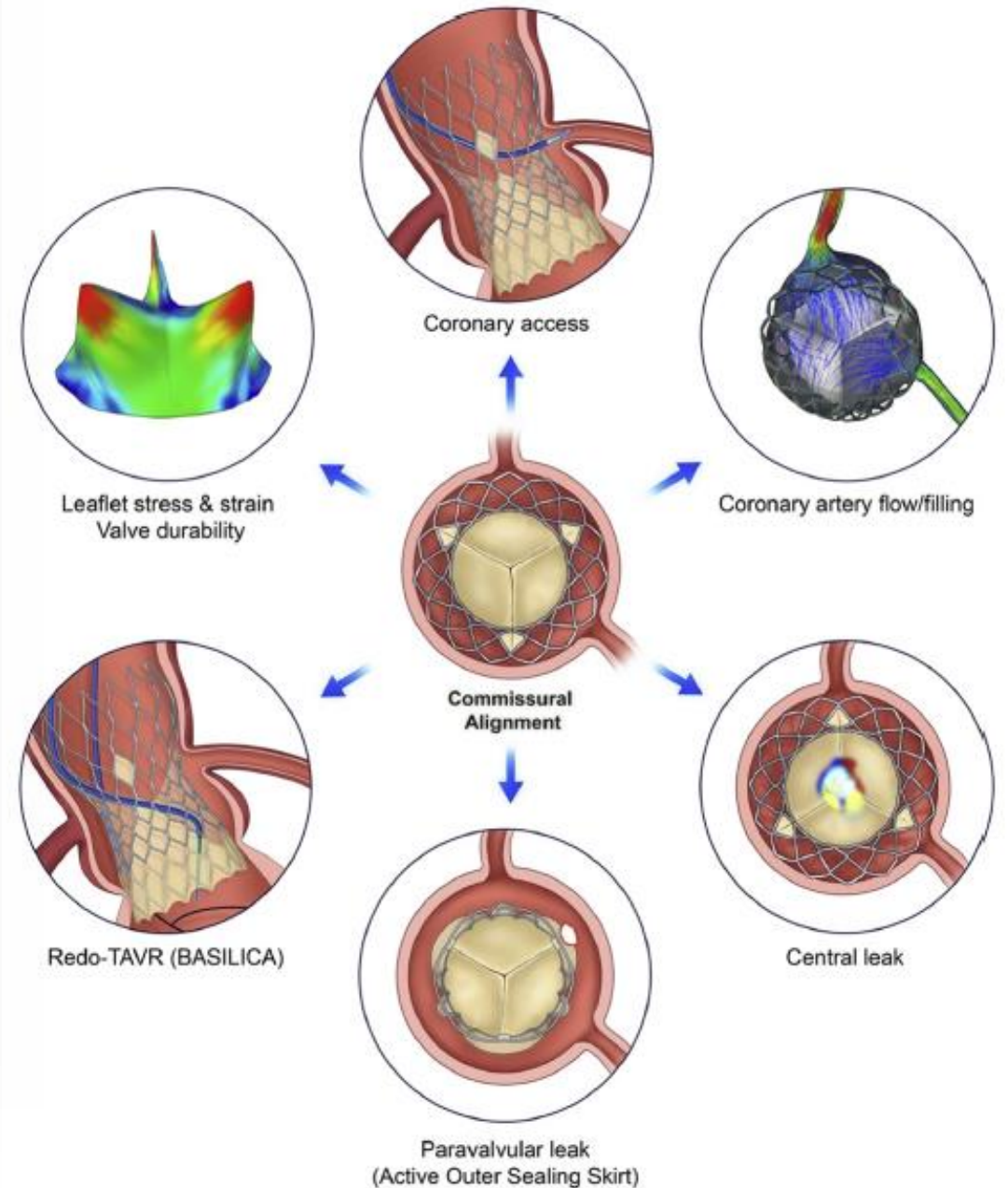
Commissural Alignment



Why does Commissural Alignment matter?

- **Coronary access in taller THV**
- Reducing risk of coronary obstruction in TAV-in-SAV
- Increase likelihood of redo TAVR by reducing risk of sinus sequestration and coronary obstruction
- Long-term impact on durability? Increased HALT or gradient with misalignment?
- Leaflet modification not feasible if commissural post faces the coronary

FIGURE 1 Possible Impact of Commissural Alignment in TAVR



Obtaining commissural alignment in TAVR can result in easier coronary access, better coronary artery flow/filling, reduce the risk of mild



Unrestricted coronary access

The largest accessible stent cell area¹



ACURATE neo2™ Aortic Valve System Small

SAPIEN™ 3 23 mm

Evolut™ R 26 mm

NAVITOR 29 mm²

Area

489.0 mm²

32.9 mm²

15.7 mm²

68.7 mm²

Diameter

18.5 mm

4.9 mm

3.9 mm

8.1 mm

1. Meier D et al., Coronary Access Following Redo TAVR. Impact of THV Design, Implant Technique, and Cell Misalignment, JACC CI 2022 <https://doi.org/10.1016/j.jcin.2022.05.005>
 2. NAVITOR measurements on file at BSC.



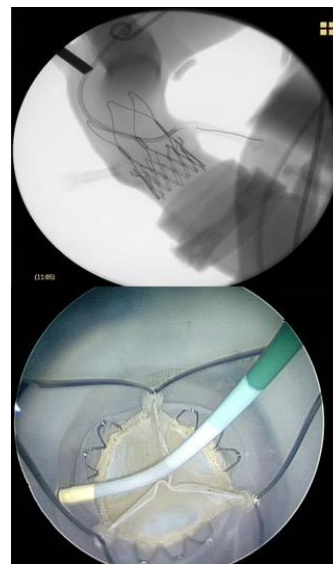
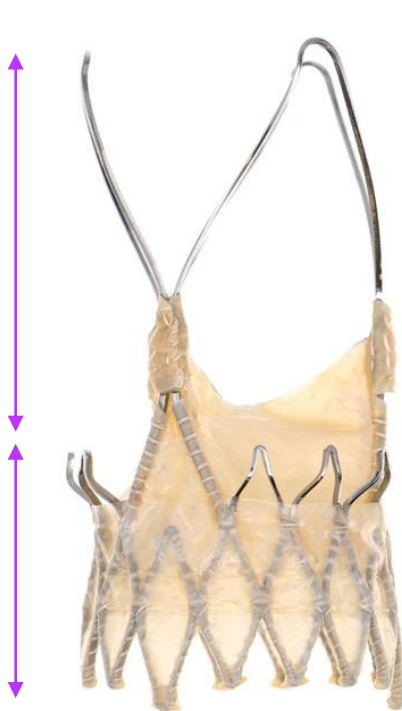
Unrestricted coronary access

Open upper stabilization arches allow for unique coronary access techniques.

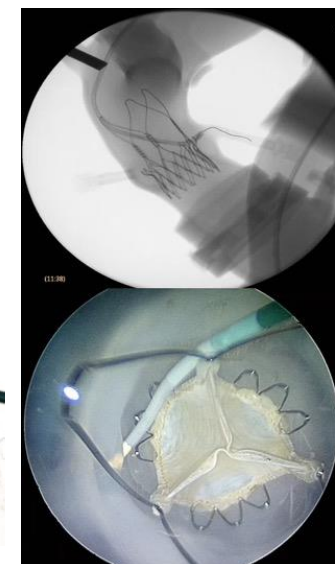
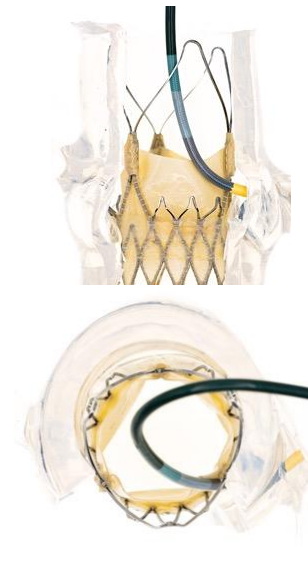
Split-level design

Open upper frame

Stent body

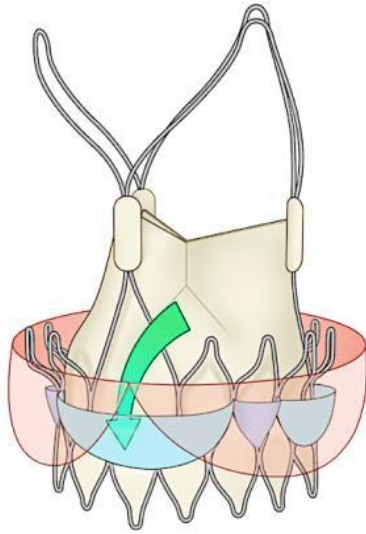


Open stabilization arches allow sufficient space to manipulate catheter

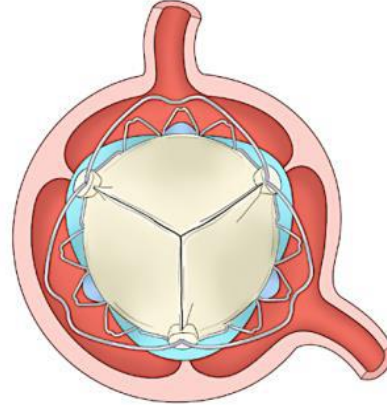


Catheter able to bypass commissural posts

ACURATE neo2 implantation with commissural alignment

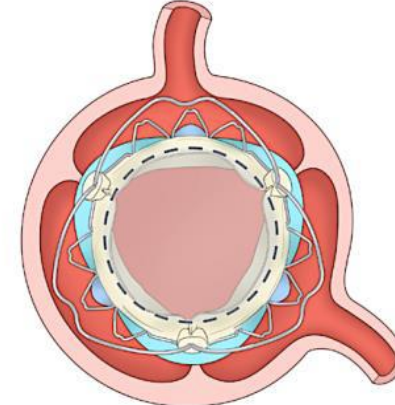


PARAVALVULAR LEAK



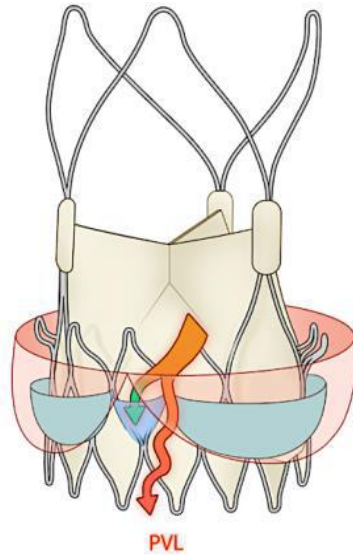
Optimal effect of
outer sealing skirt

EFFECTIVE ORIFICE AREA

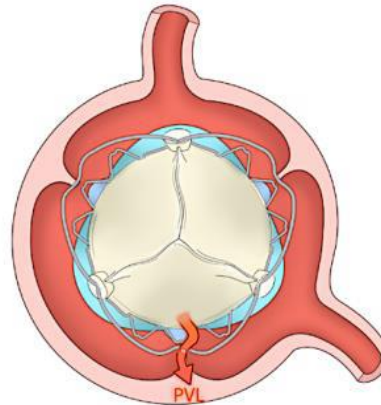


Optimal expansion of
commissural posts

ACURATE neo2 implantation with severe commissural misalignment

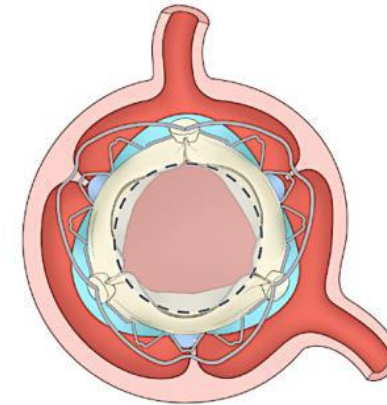


PARAVALVULAR LEAK



Suboptimal position of largest
pouch of outer sealing skirt

EFFECTIVE ORIFICE AREA

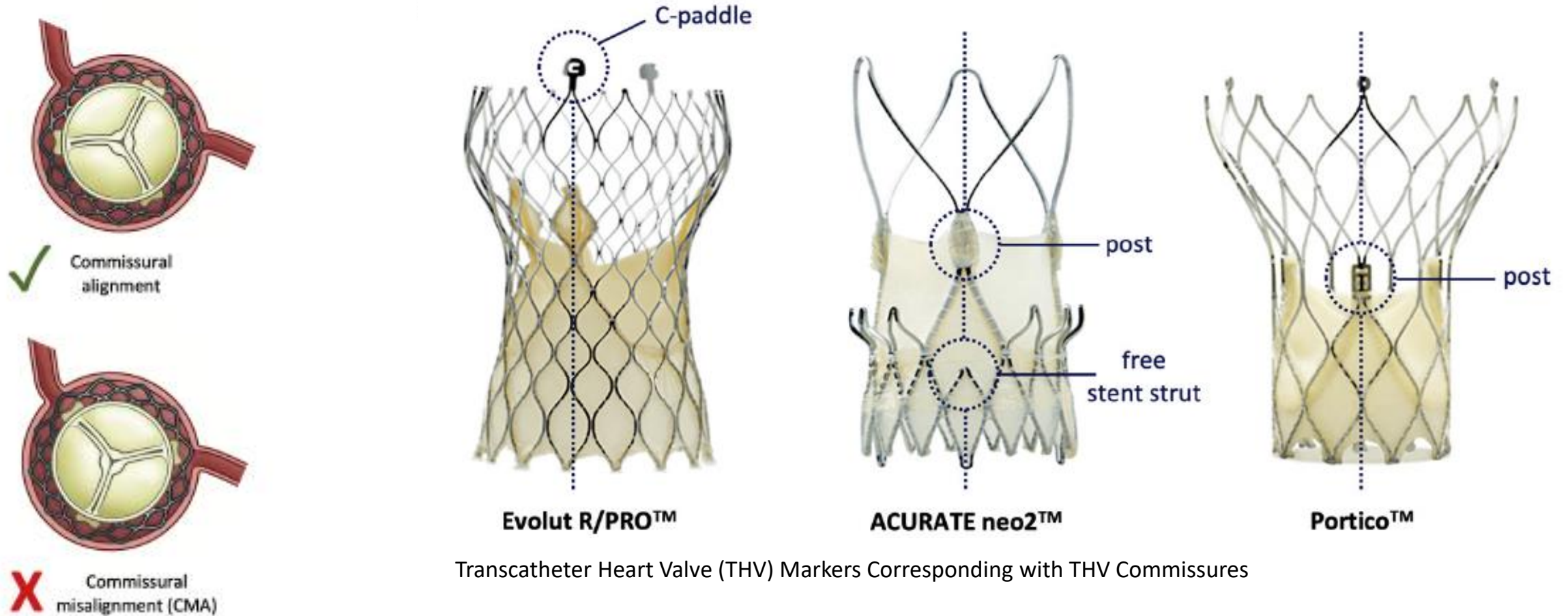


Suboptimal expansion of
commissural posts

COMALIGN -The Commissural Alignment Study

N=60 TAVR patients implanted with Evolut R/Pro, ACURATE *neo2* or Portico

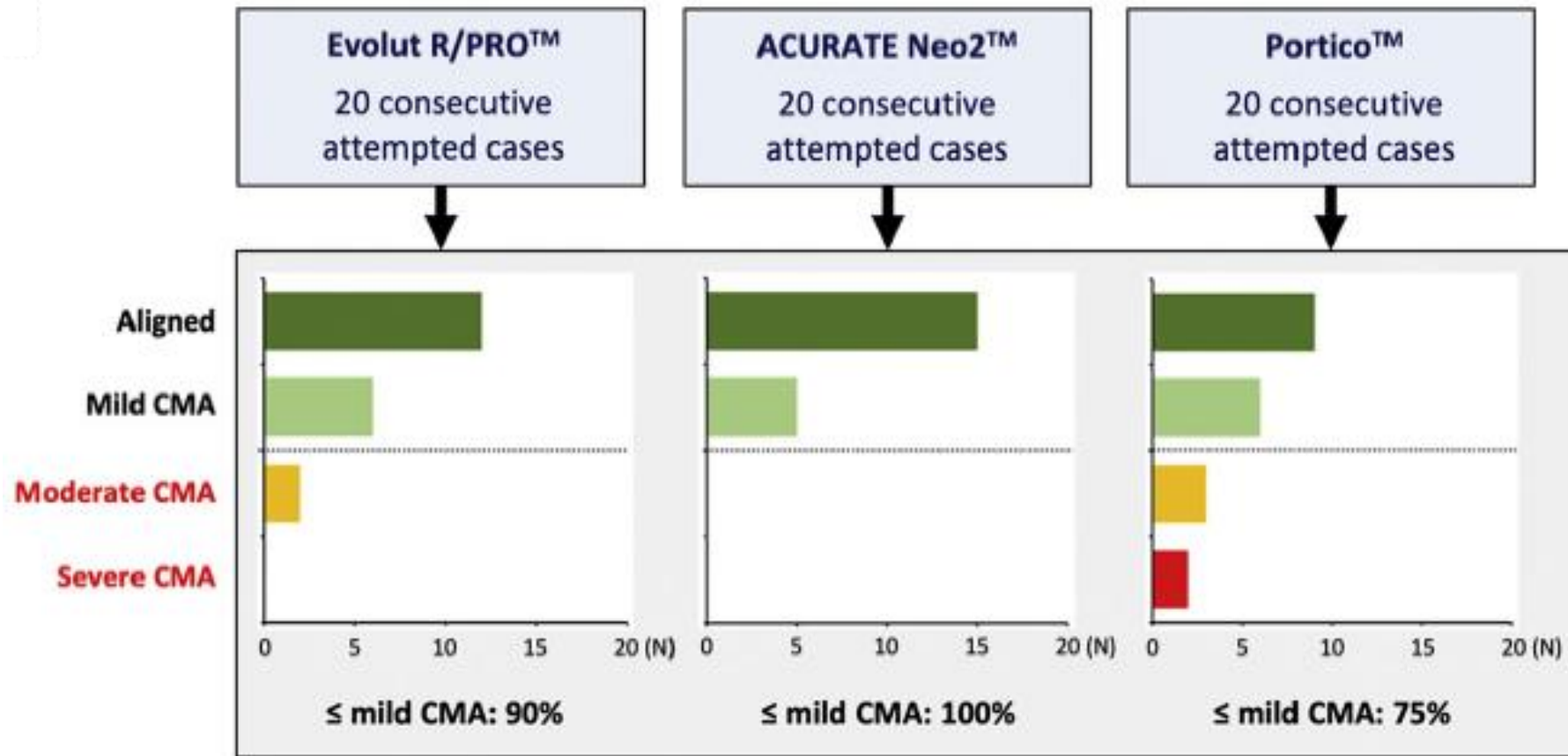
Prospective, commissural alignment study (COMALIGN) testing THV implantation with neo-commissural alignment for 3 different THV platforms. Pre-procedural planning was based on CT scan.



Transcatheter Heart Valve (THV) Markers Corresponding with THV Commissures

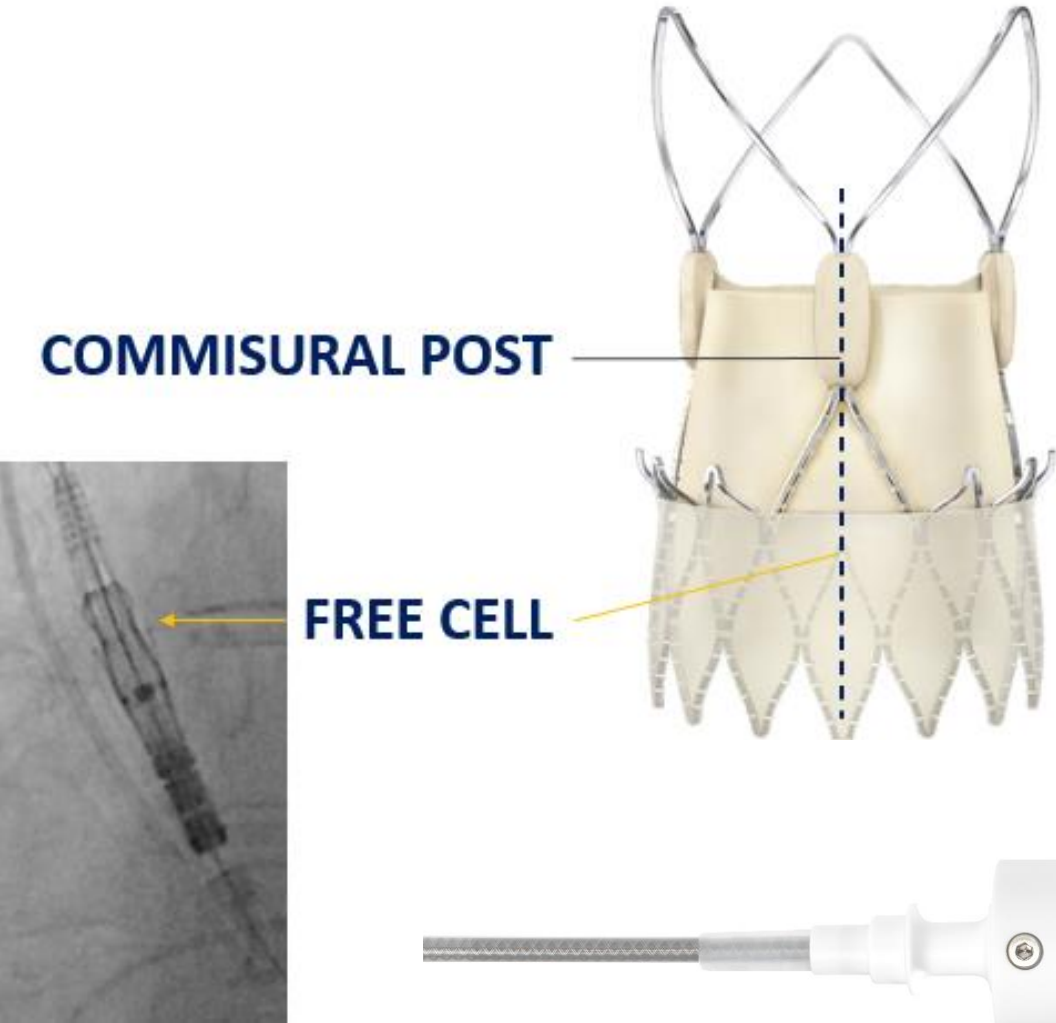
COMALIGN -The Commissural Alignment Study

N=60 TAVR patients implanted with Evolut R/Pro, ACURATE *neo2* or Portico



- ACURATE *neo2* (n=20): only valve to **100%** avoid moderate/severe misalignment and demonstrate **100%** optimal rotation.
- Evolut R/PRO (n=20): **10%** moderate/severe misalignment and 3 cases of non-optimal rotation.
- Portico (n=20): **25%** moderate/severe misalignment and 5 cases of non-optimal rotation.

Commissural alignment

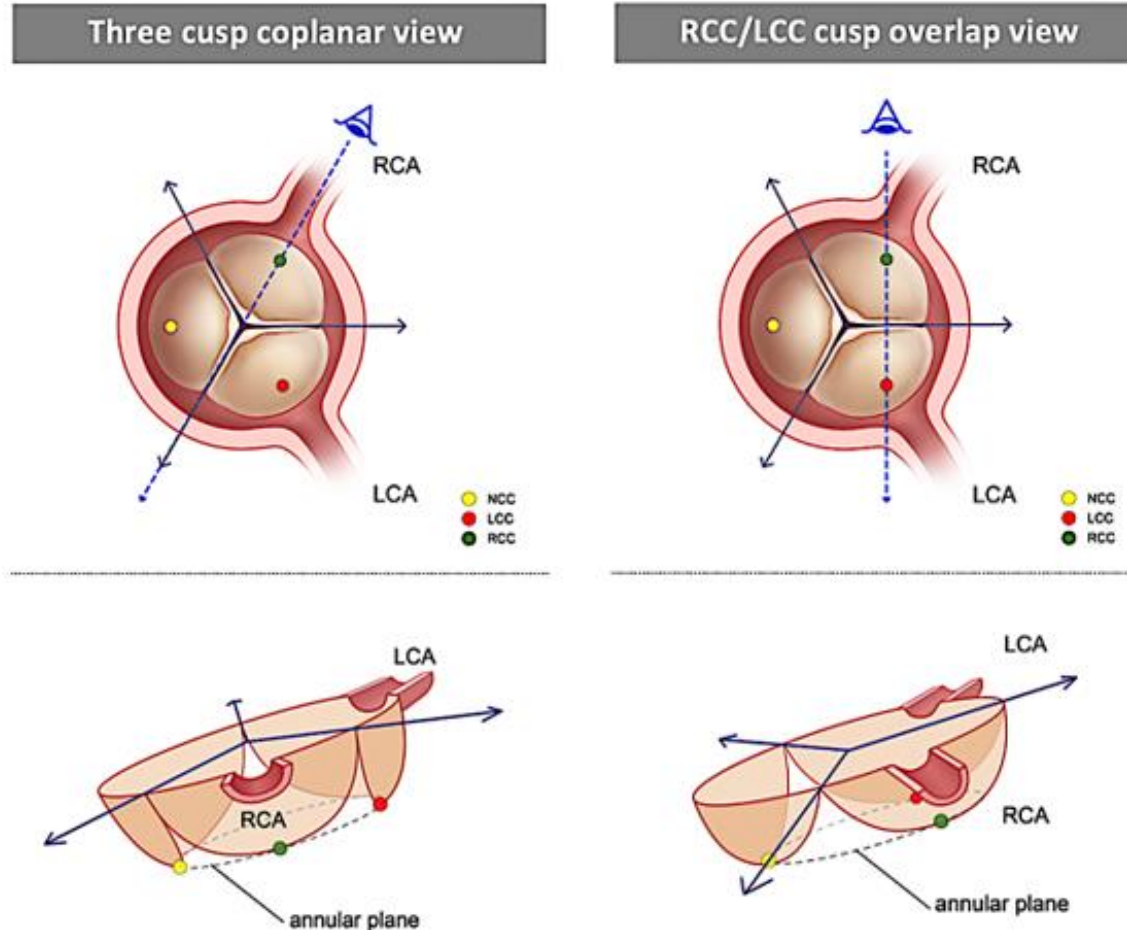


ACURATE *neo2*TM THV markers corresponding with THV commissures



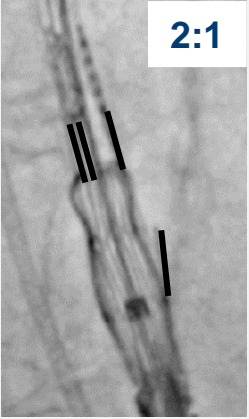
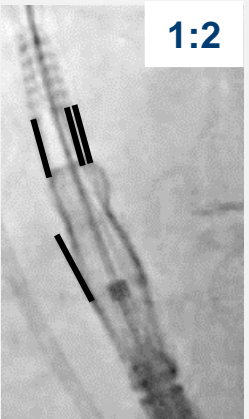
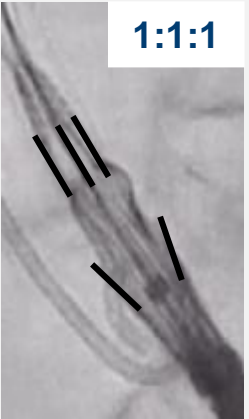




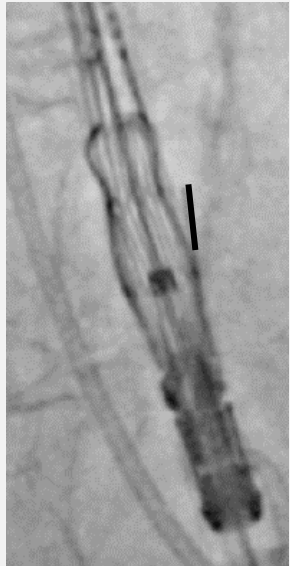

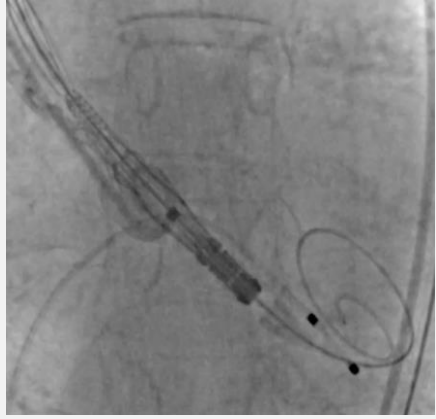


Commissural alignment

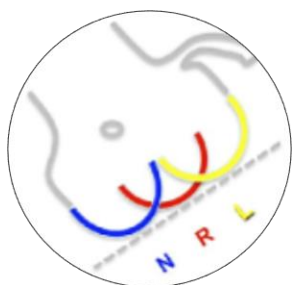
Understanding **commissural orientation** from different fluoroscopic projections



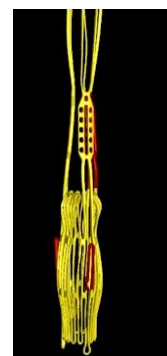
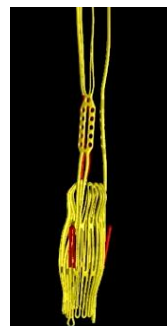
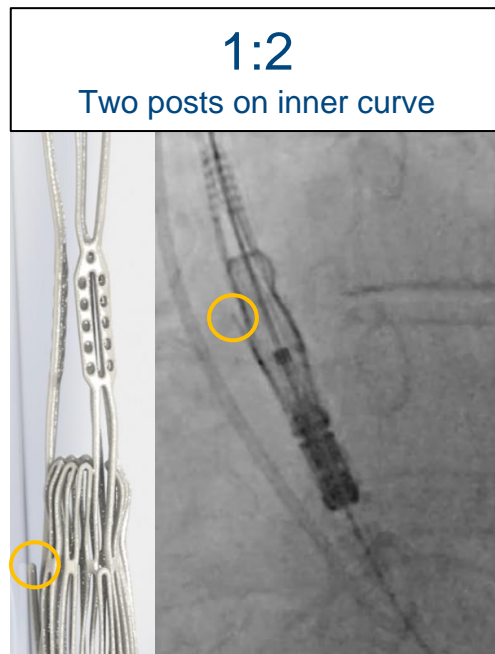
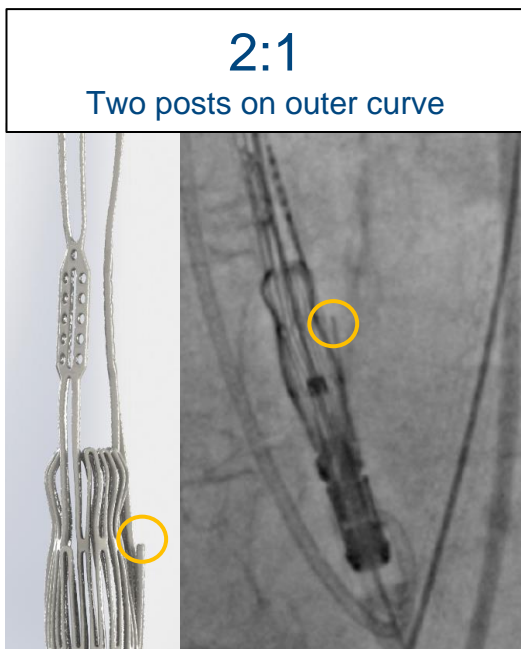
Commissural alignment

Step 1 : INSERT	Step 2: ALIGN	Step 3: CONFIRM	Step 4: IMPLANT
 <p>6 o'clock</p>	<p style="text-align: center;">3 Cusp View (ACURATE <i>neo2</i> marker at top of pigtail) </p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>2:1</p>  </div> <div style="text-align: center;"> <p>OR</p> </div> <div style="text-align: center;"> <p>1:2</p>  </div> <div style="text-align: center;"> <p>OR</p> </div> <div style="text-align: center;"> <p>1:1:1</p>  </div> </div> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;">  <p>Rotate CW away from operator</p> </div> <div style="text-align: center;">  <p>Rotate CCW towards operator</p> </div> <div style="text-align: center;">  <p>No rotation Proceed to Step 3</p> </div> </div>	<p style="text-align: center;">Cusp Overlap </p>  <p style="text-align: center;">In cusp overlap one free cell should be on the inner curvature</p>	<p style="text-align: center;">3 Cusp View </p>  <p style="text-align: center;">After alignment, allow handle to rotate back slowly in cradled hands</p>
<p>Position handle with safety button at 6 o'clock facing down</p>	<p>Rotate front part of the handle until two free cells are symmetrical visible in 3 cusp view</p> <p style="color: blue;">Most cases alignment achieved between 0.5 and 1.5 handle rotations (180° to 540°)</p>	<p style="color: blue;">If incorrect - Rotate either CW or CCW and revert to step 2</p>	<p style="color: blue;">Proceed with ACURATE <i>neo2</i> implantation steps</p>

Commissural alignment



3 cusp view

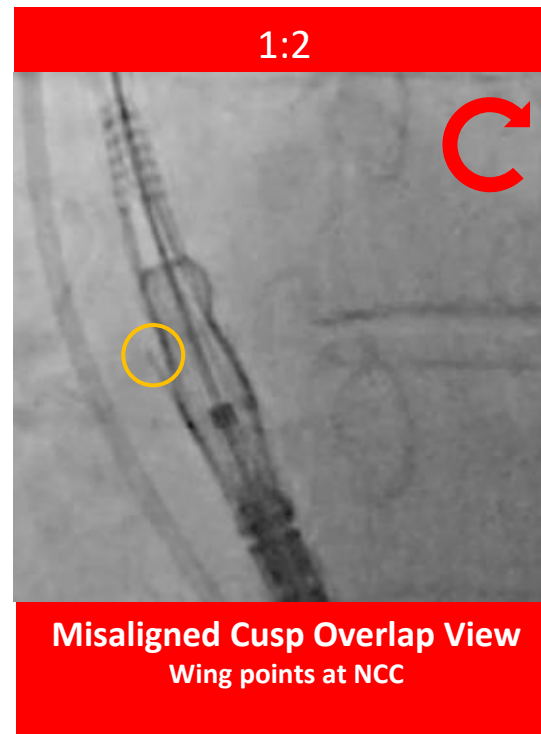
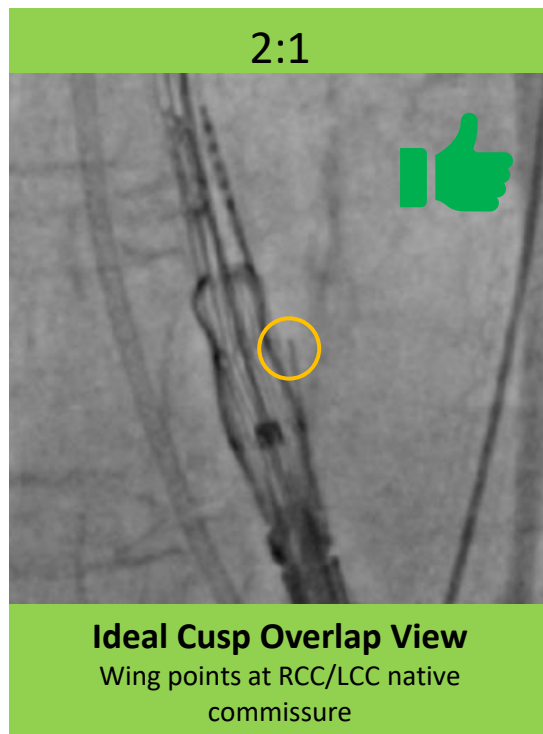
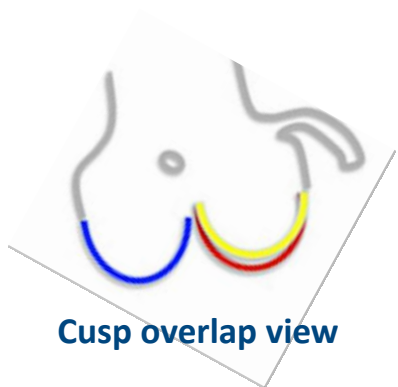


Aligned in 3 cusp view

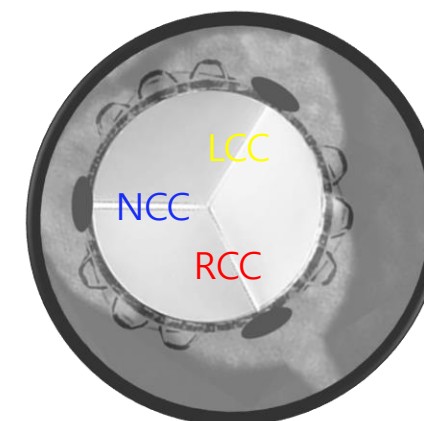
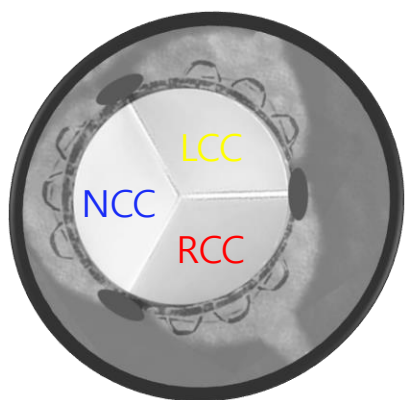
Misaligned

Commissural alignment

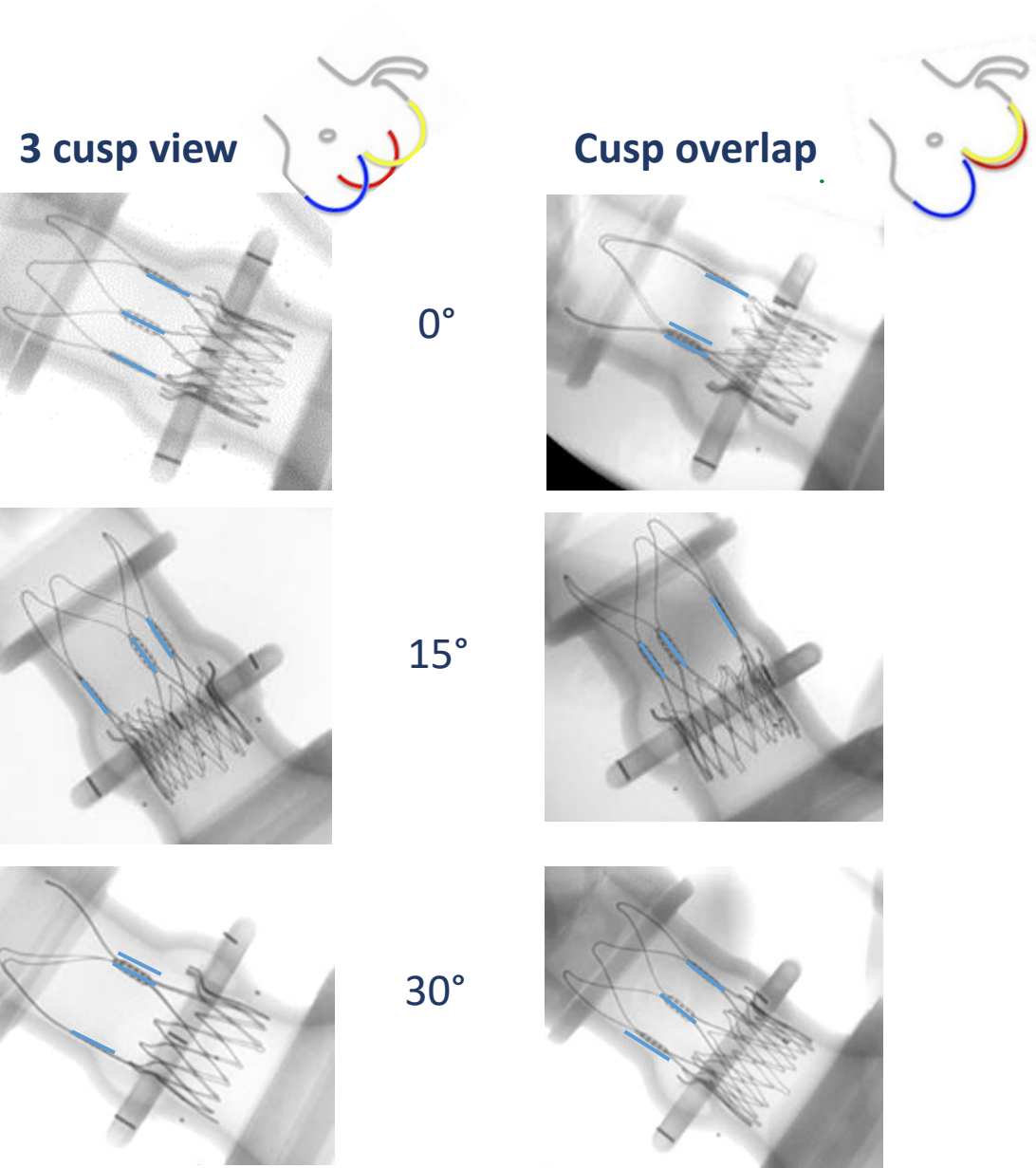
Confirmation



Verify correct rotational position
If rotation required use information from 3 cusp view to go CW or CCW

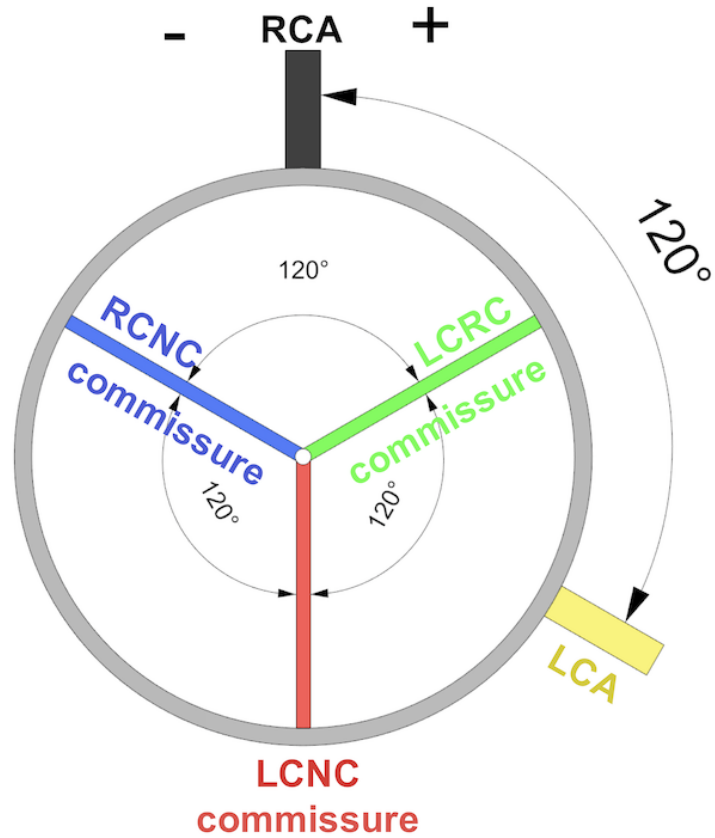


Commissural alignment after THV implantation

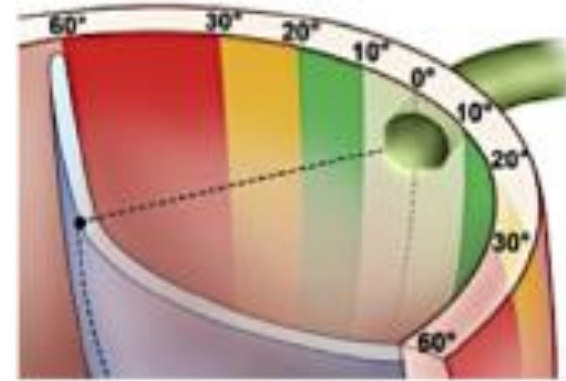


LIMITATIONS: variations in coronary eccentricity

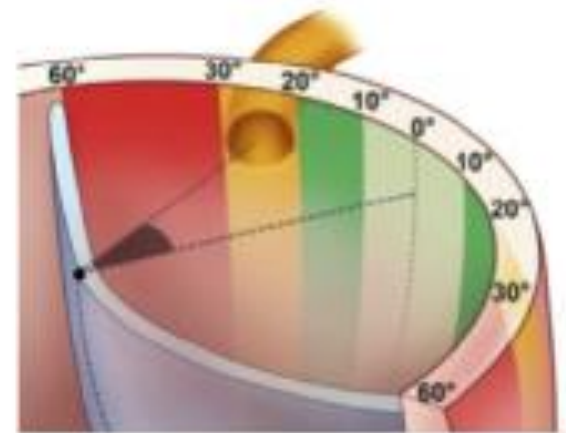
1a



Ideally symmetrical aortic anatomy



Centered



Moderate eccentricity

AN2 Case with Commisural Alignment

M/82

NYHA II-III Dyspnea

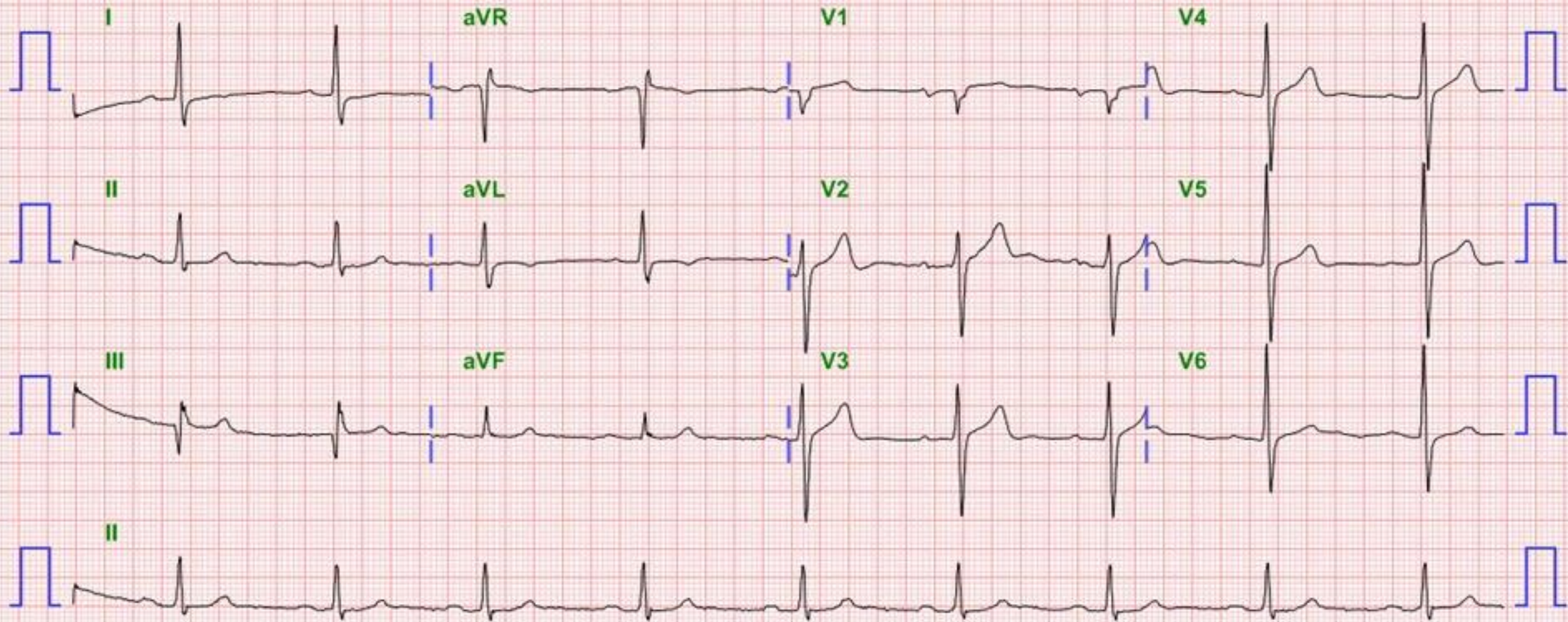
DM/HTN/DL/CKD Stage 3

h/o old MI, stroke

s/p PCI at mRCA and osLCX [14]

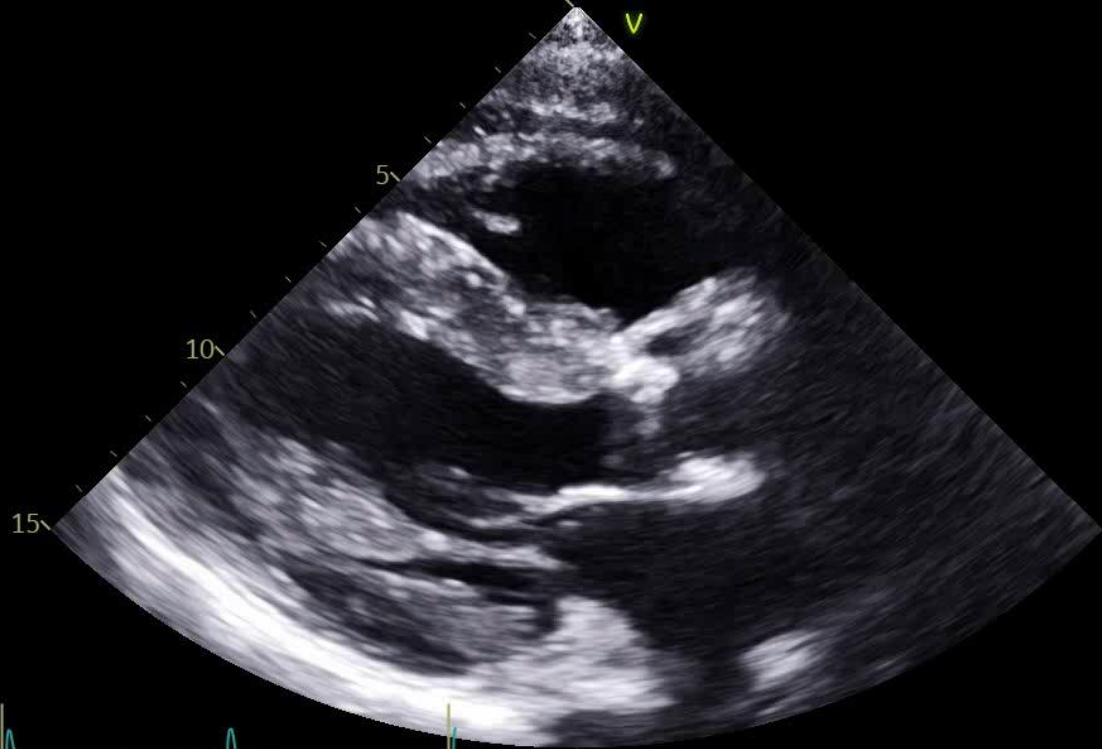
STS PROM (%) 7.77

Pre-TAVR ECG



Pre-TAVR TTE

Adapt
ACE



ShAdapt
ACE



Sharp



47
HR

Pre-TAVR TTE

Hemodynamic parameters

Tricuspid AS

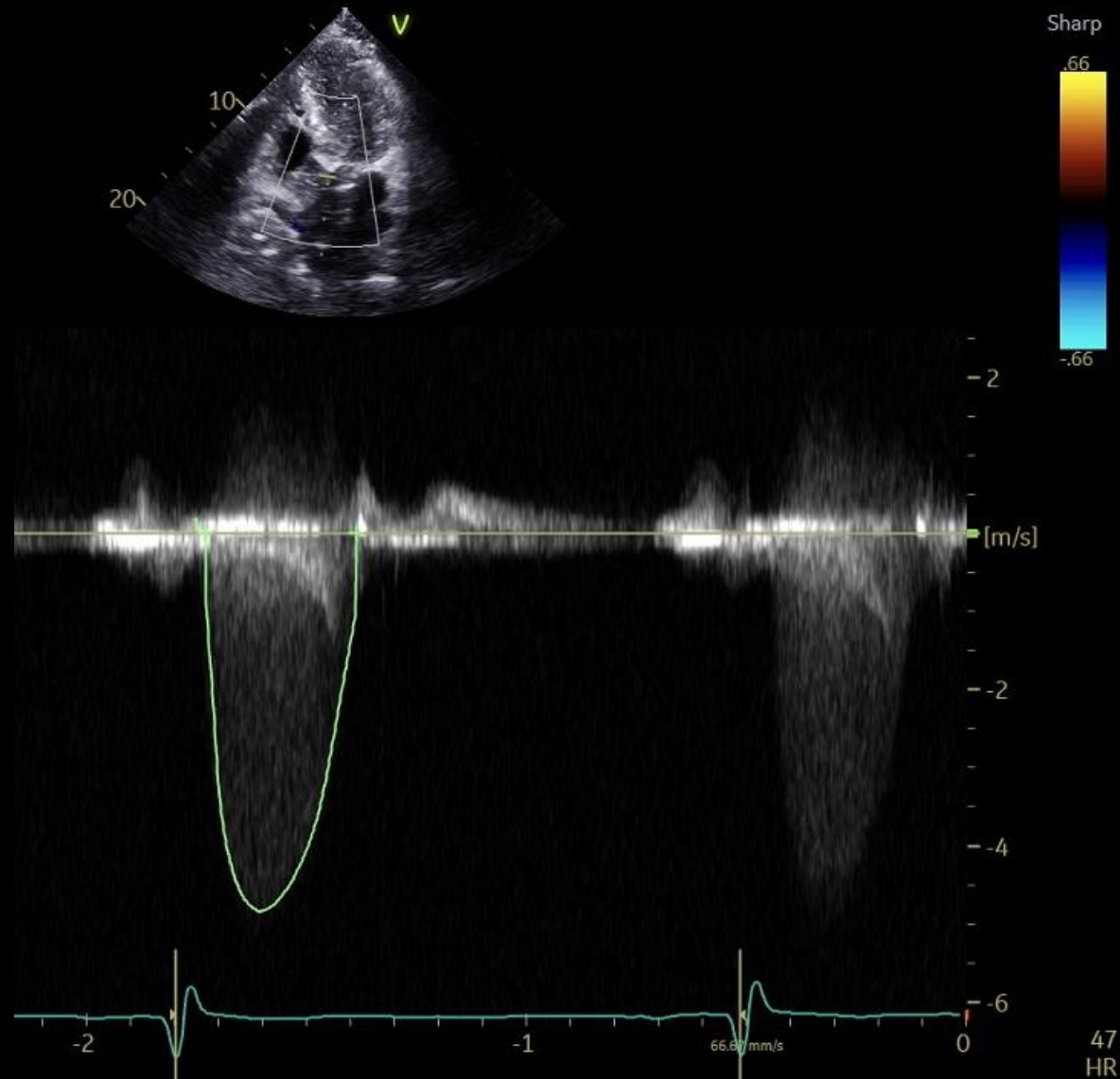
EF (%) 71.9%

Stroke volume index 57.9ml/m²

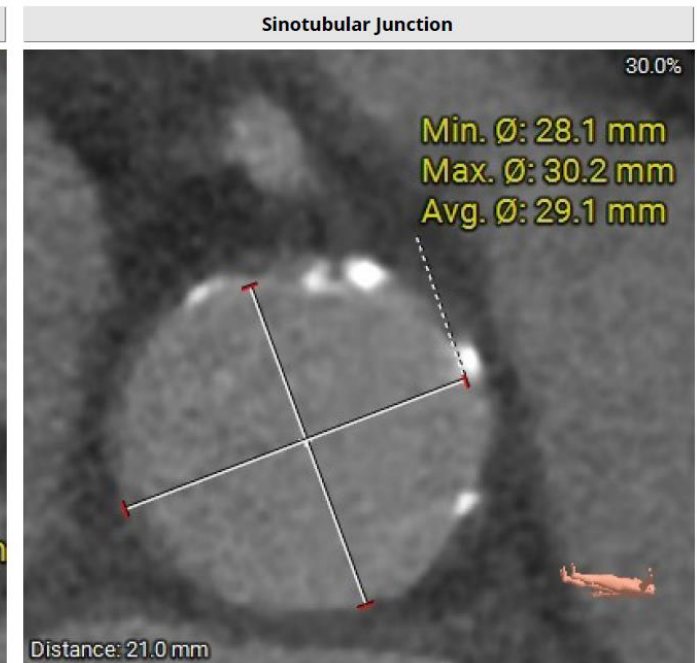
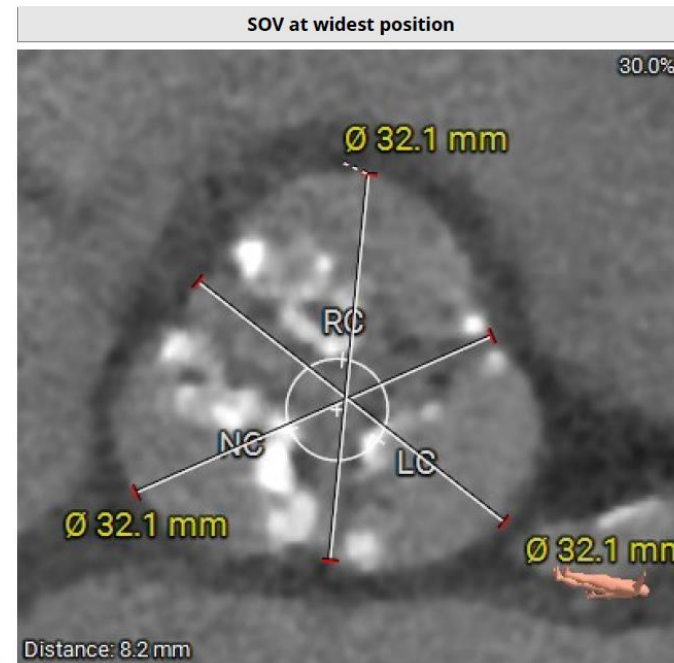
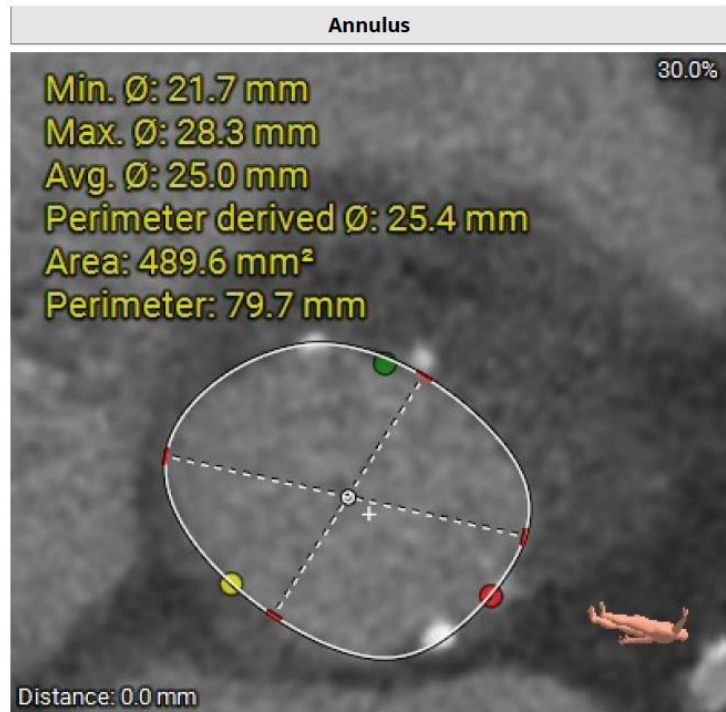
AVA (cm²) 0.80

Mean pressure gradient (mmHg) 59.6

Peak velocity (m/sec) 4.85

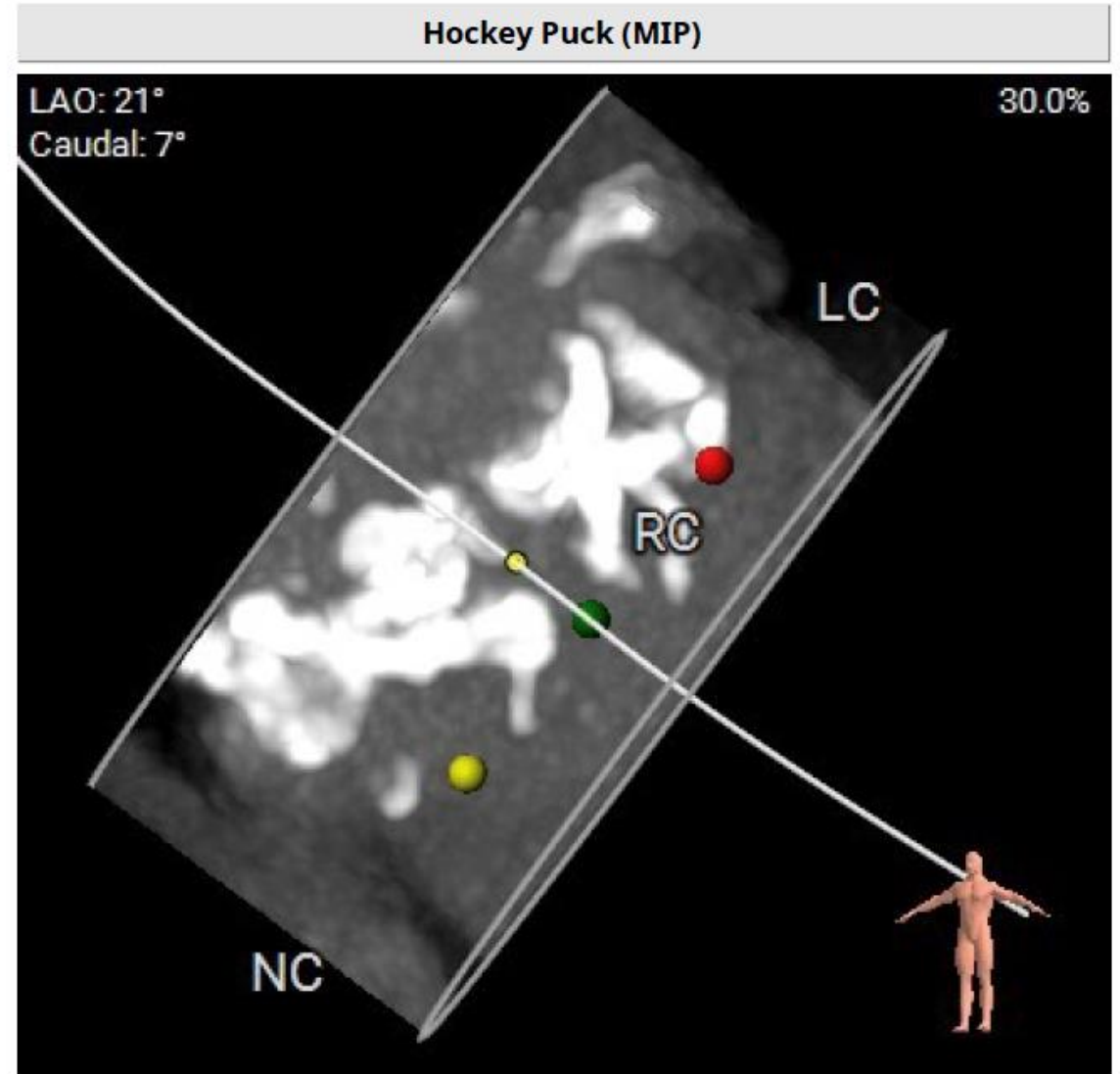
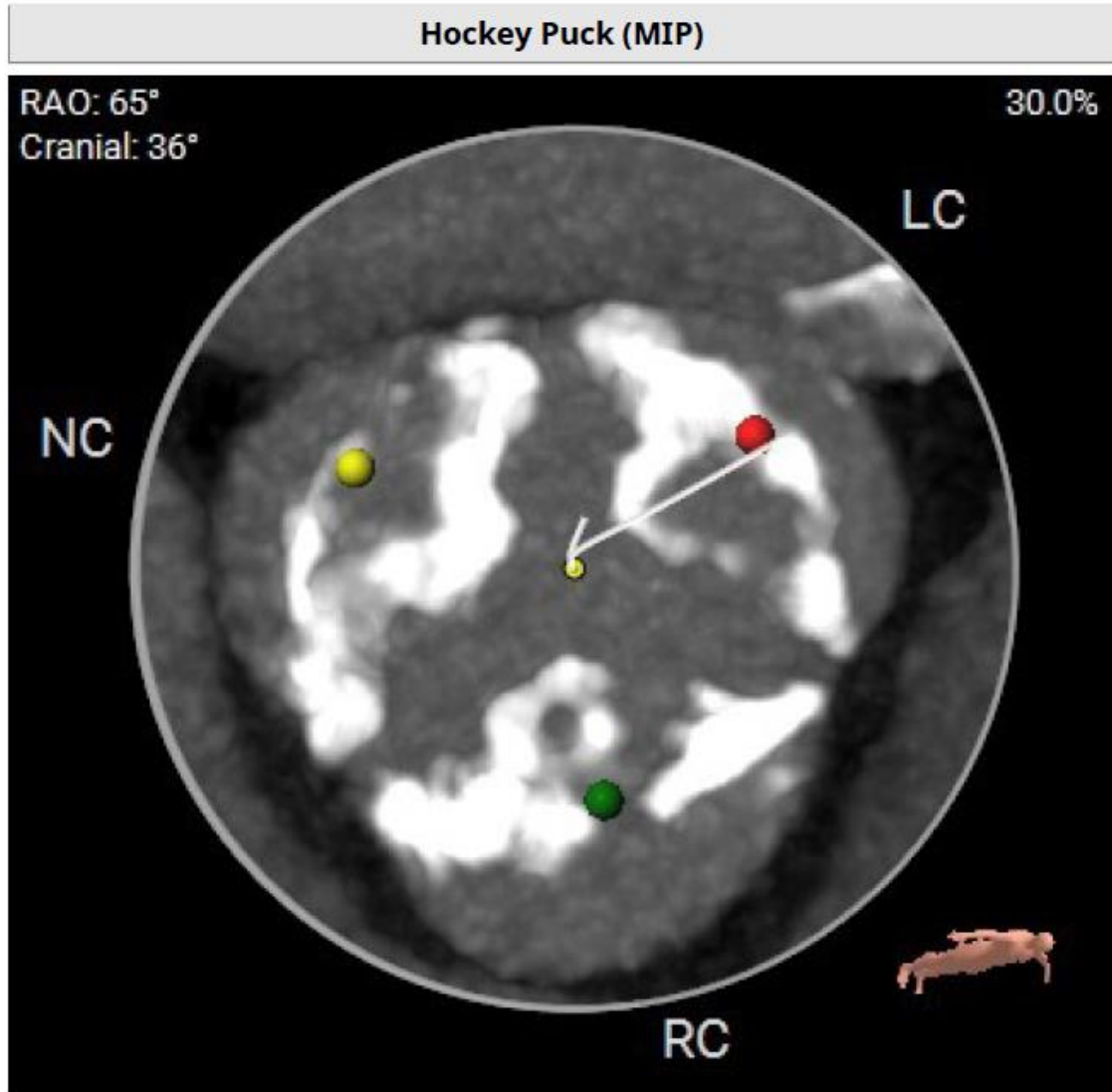


CT measurement



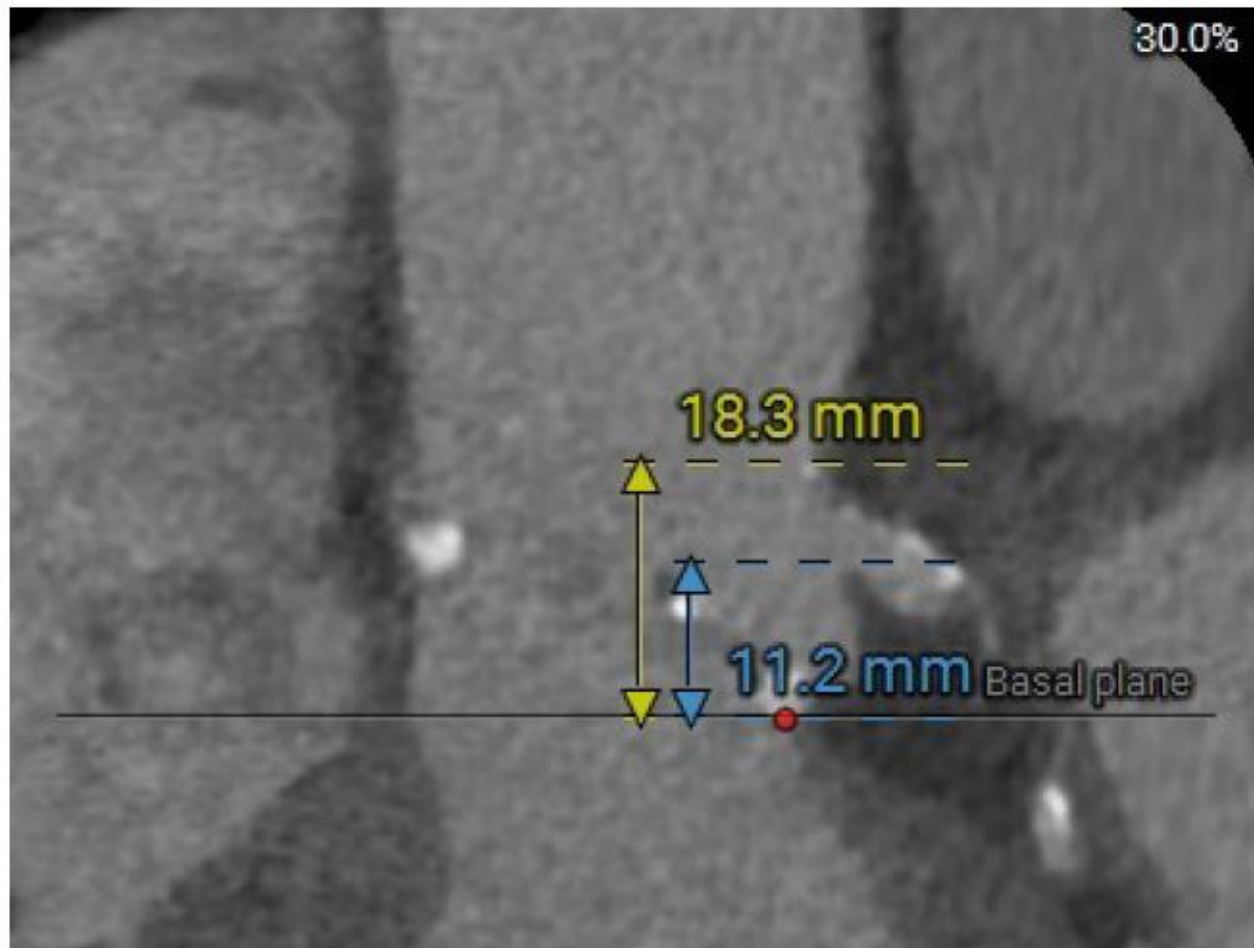
Valve Size	S – 23 mm	M – 25 mm	L – 27 mm
Aortic annulus diameter*	21 mm ≤ annulus ≤ 23 mm	23 mm < annulus ≤ 25 mm	25 mm < annulus ≤ 27 mm
Aortic annulus perimeter	66 mm ≤ annulus ≤ 72 mm	72 mm < annulus ≤ 79 mm	79 mm < annulus ≤ 85 mm

CT measurement: Total calcium 1245 mm³ (TH 452HU)

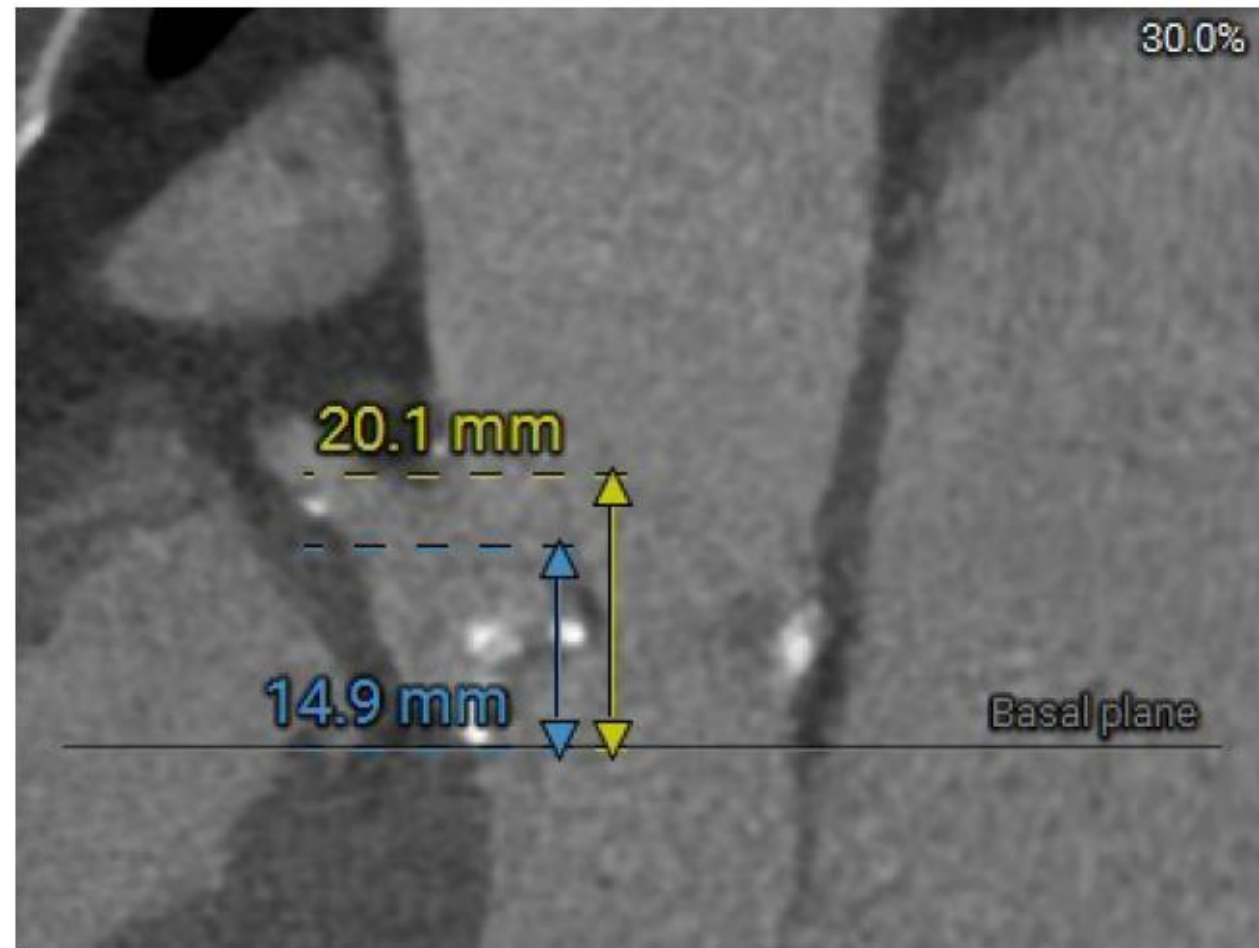


CT measurement

LCA & LCC height

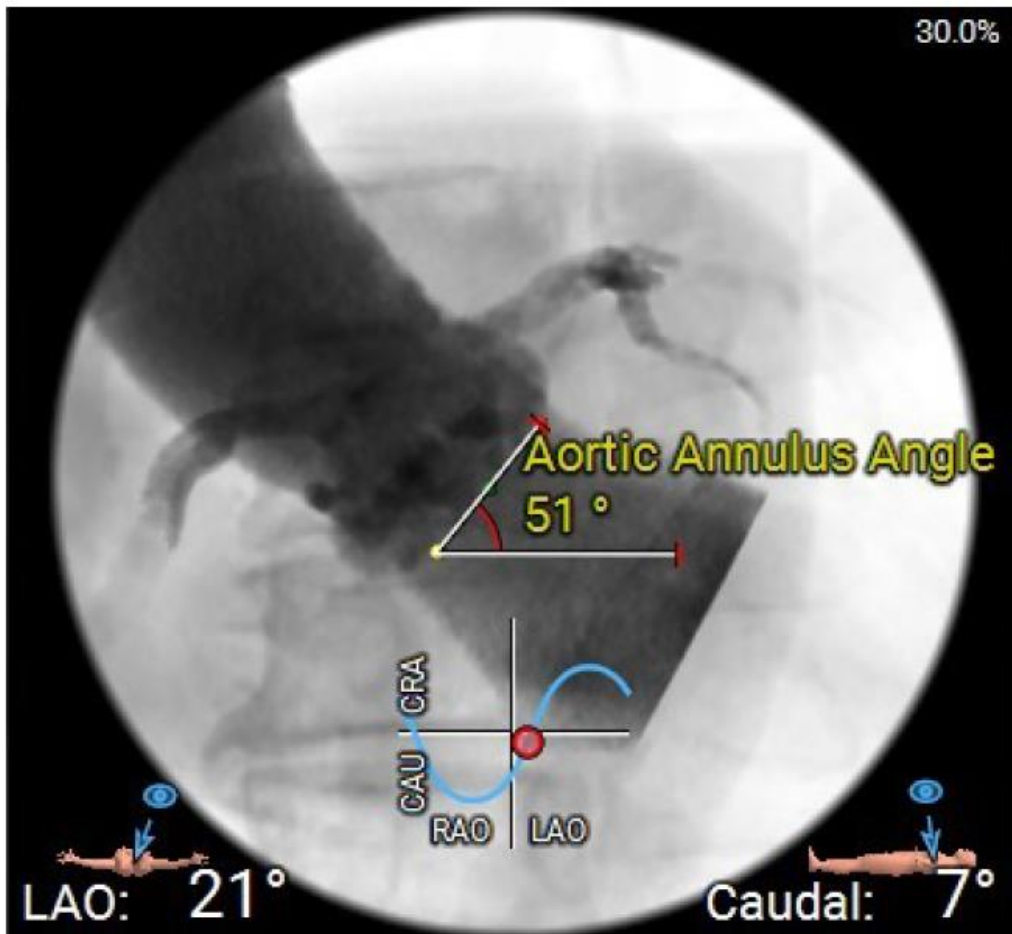


RCC & RCA height

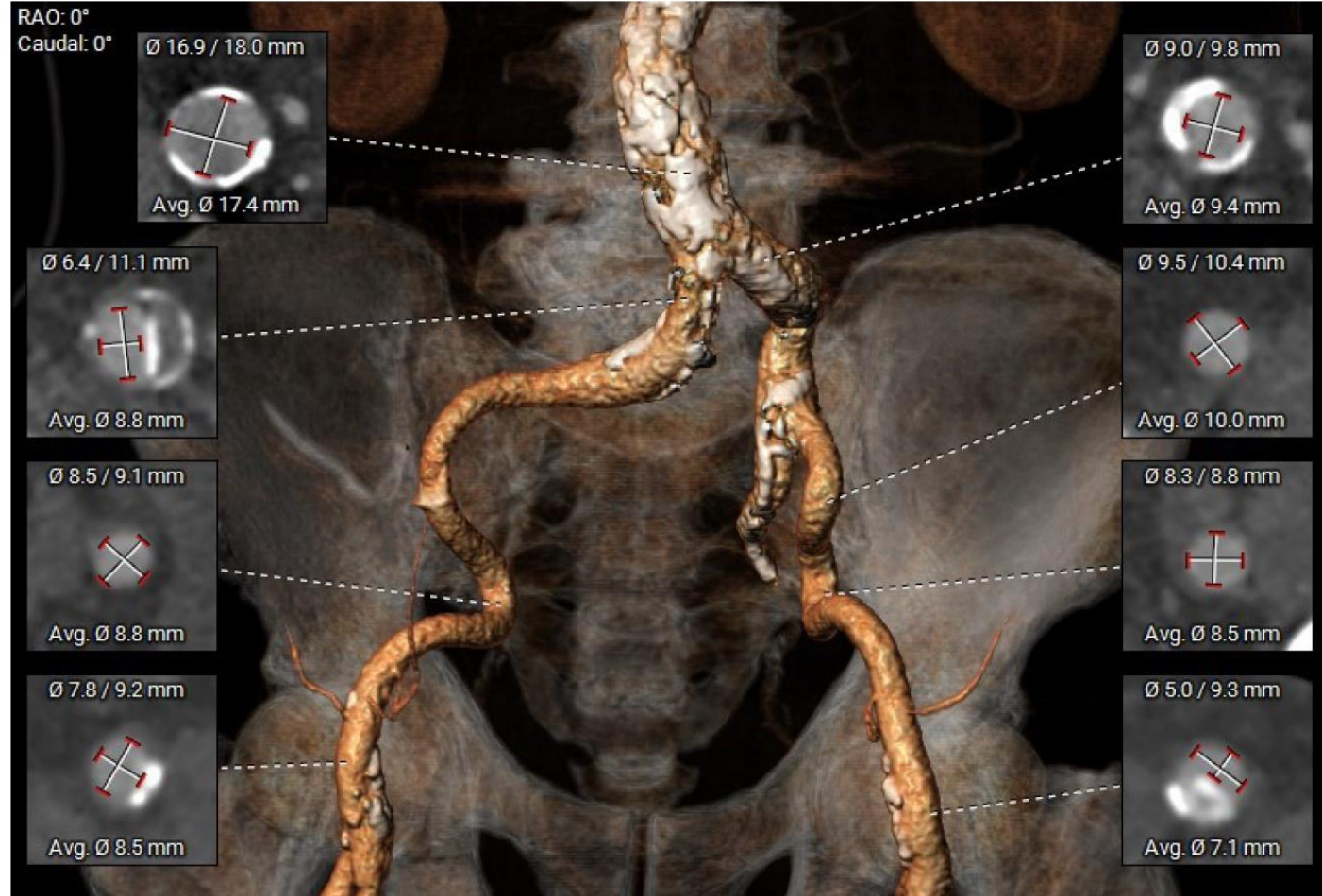


CT measurement

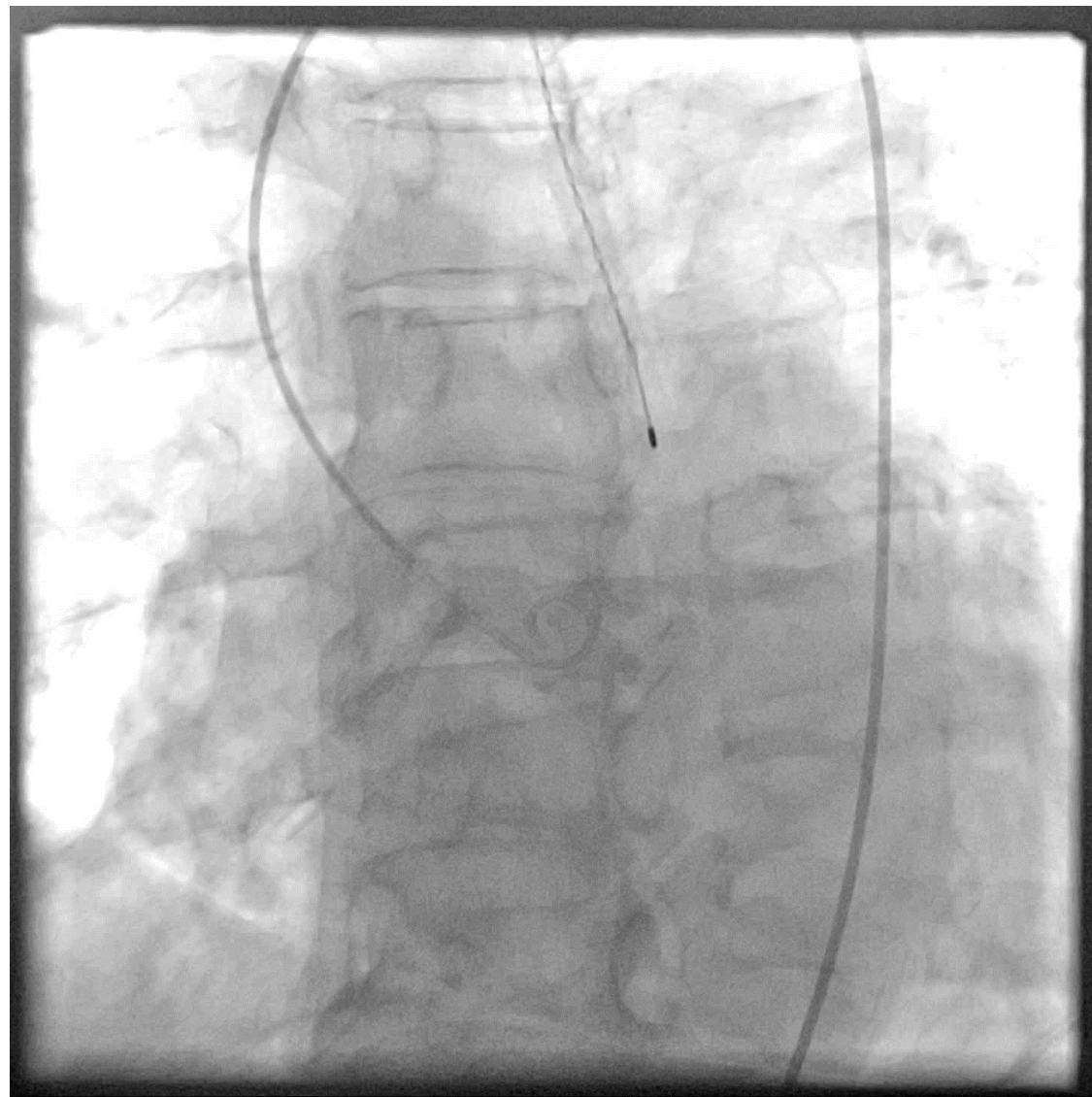
Implant View



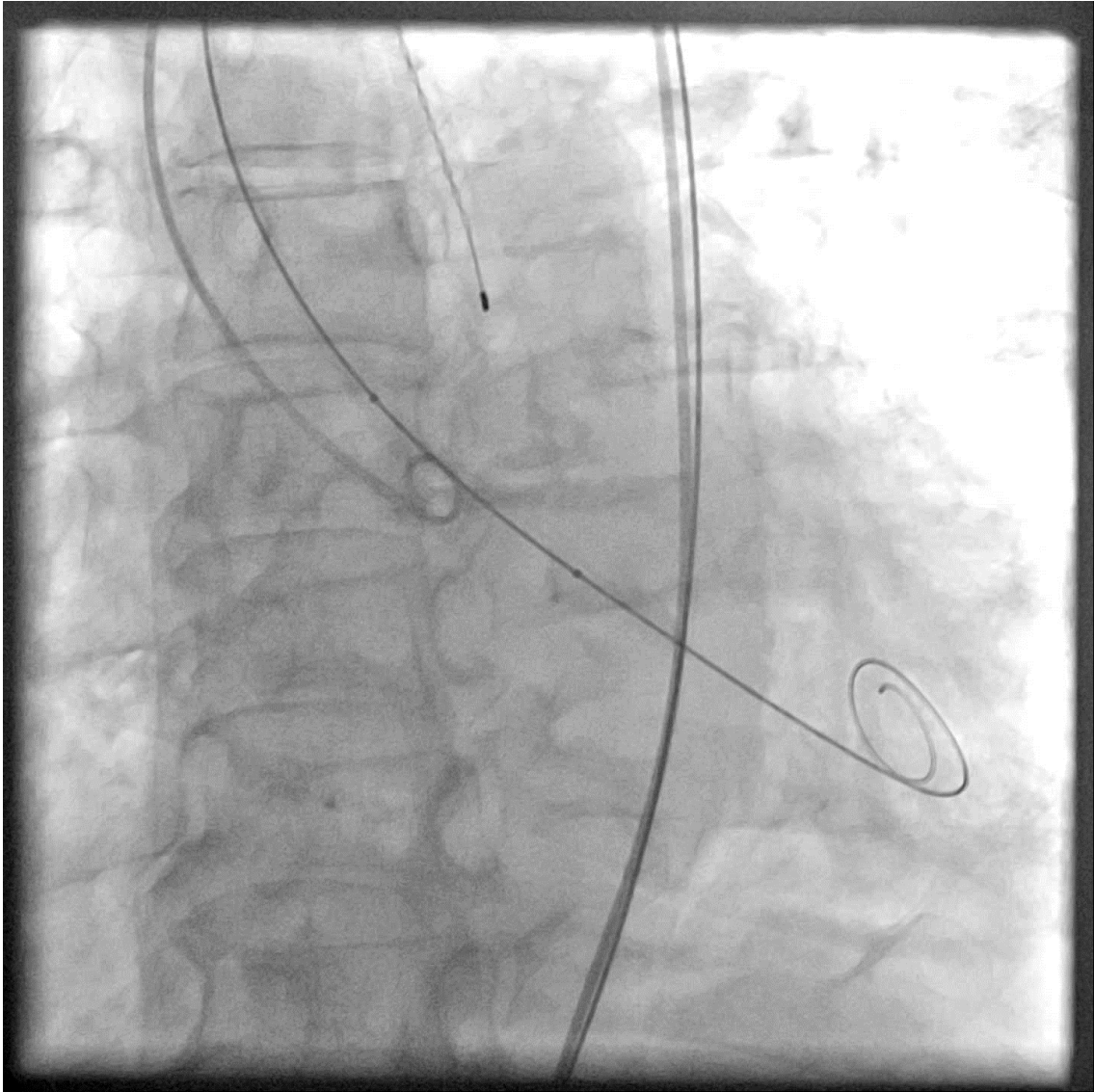
Aorto Ilio Femoral tract



Cerebral embolic protection and aortography



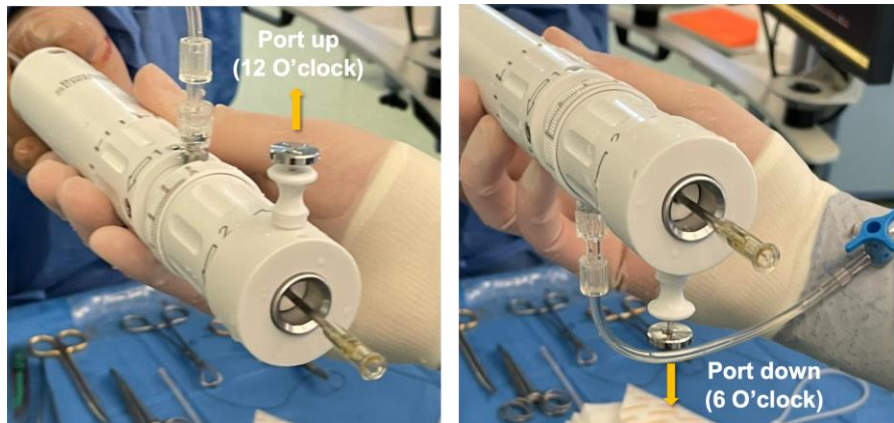
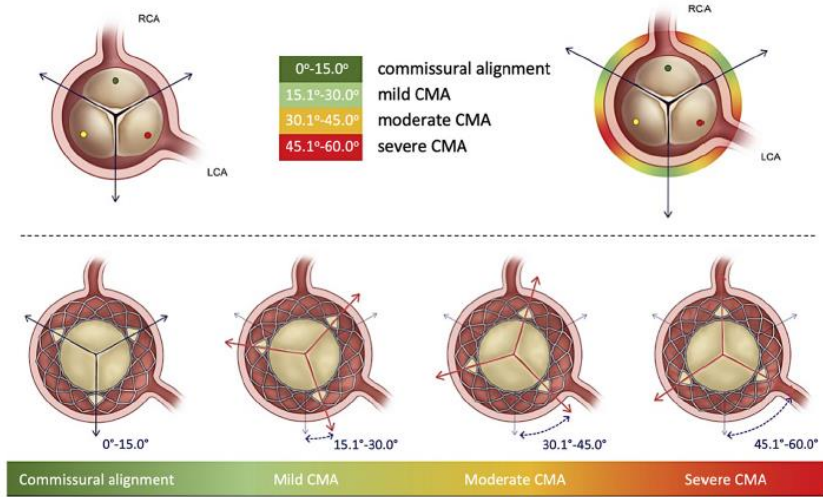
Pre-dilation: 24mm balloon under 180 BPM wire pacing



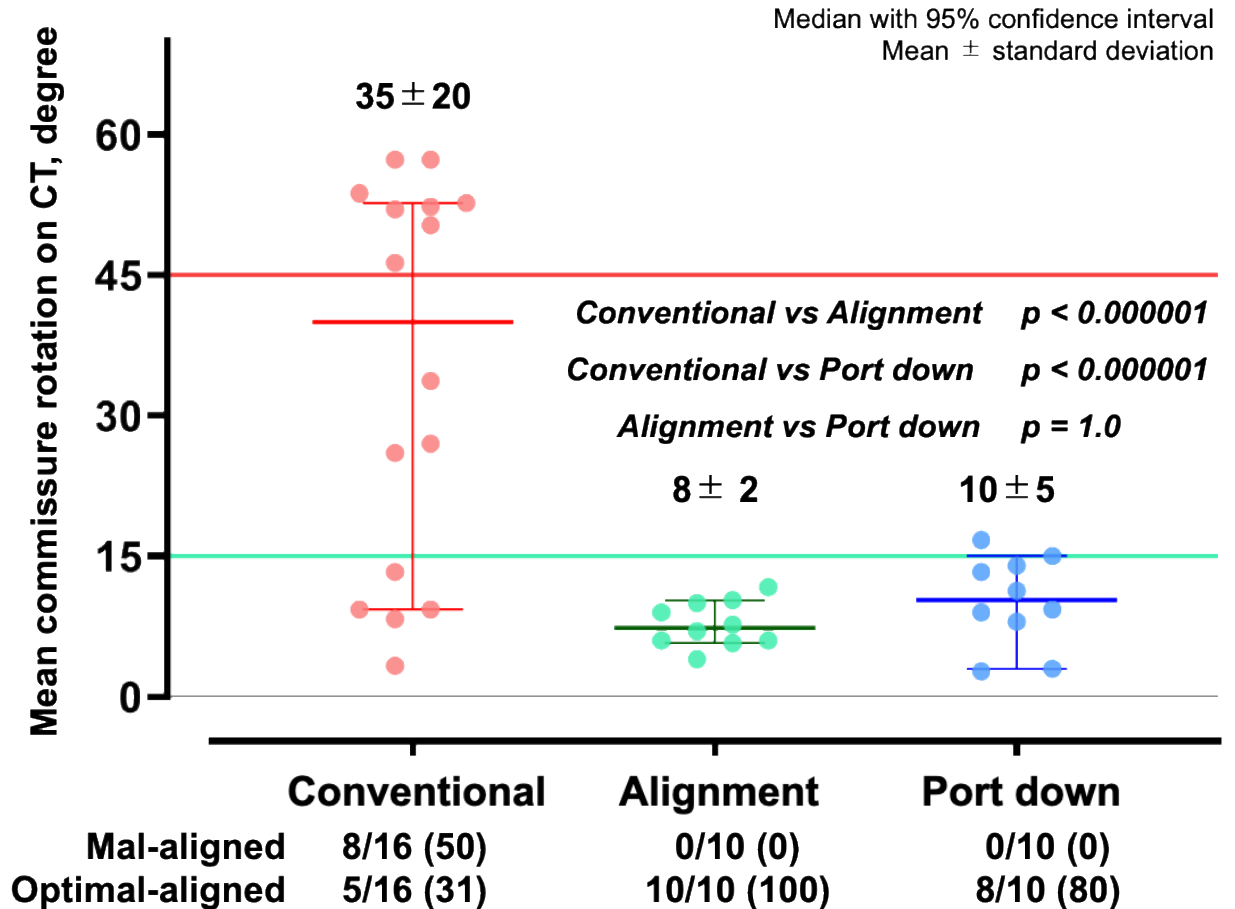
The Very First Step: flush port facing 6 o' clock

can avoid \geq moderate commissural misalignment in 100% cases using this method only

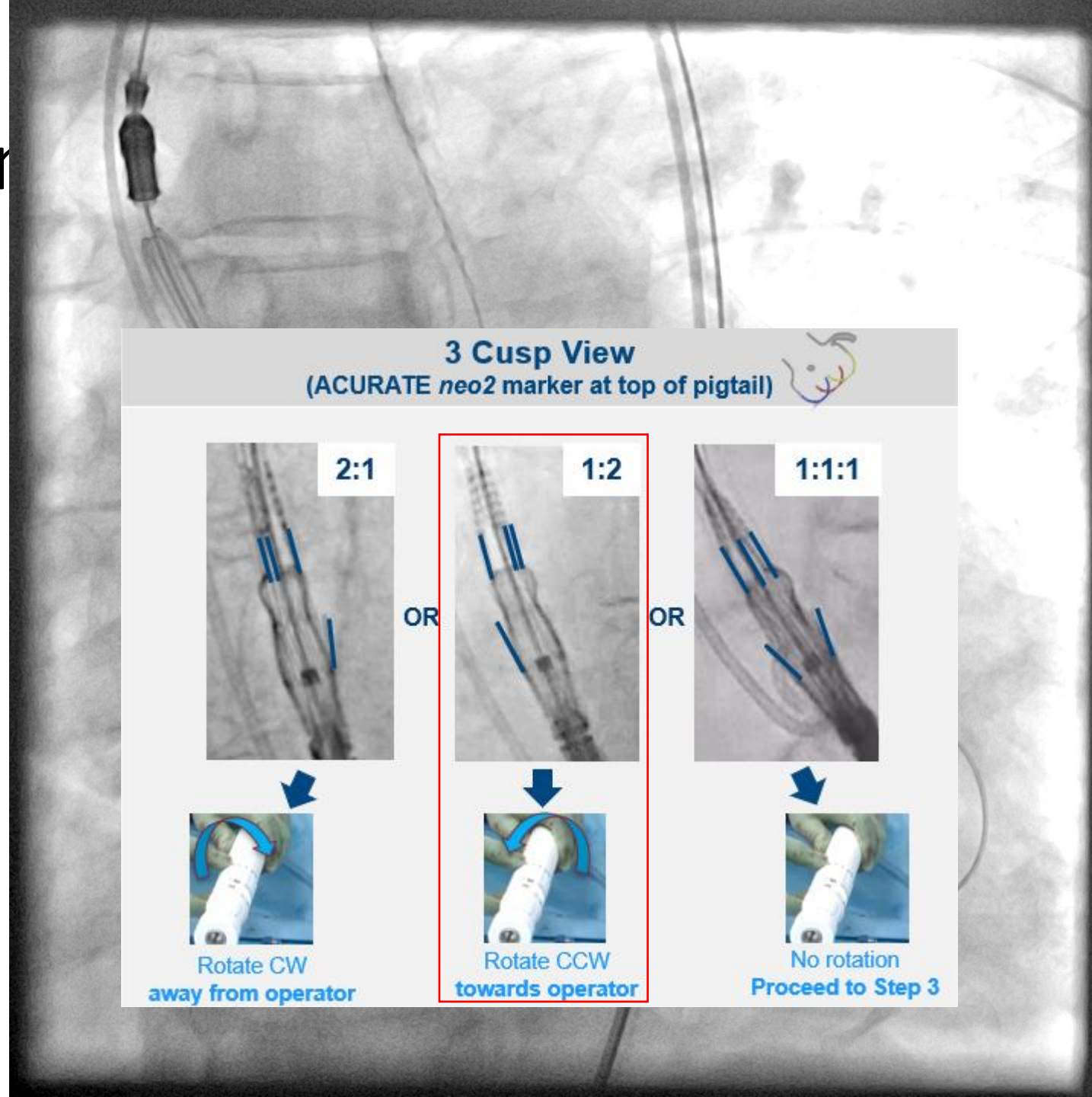
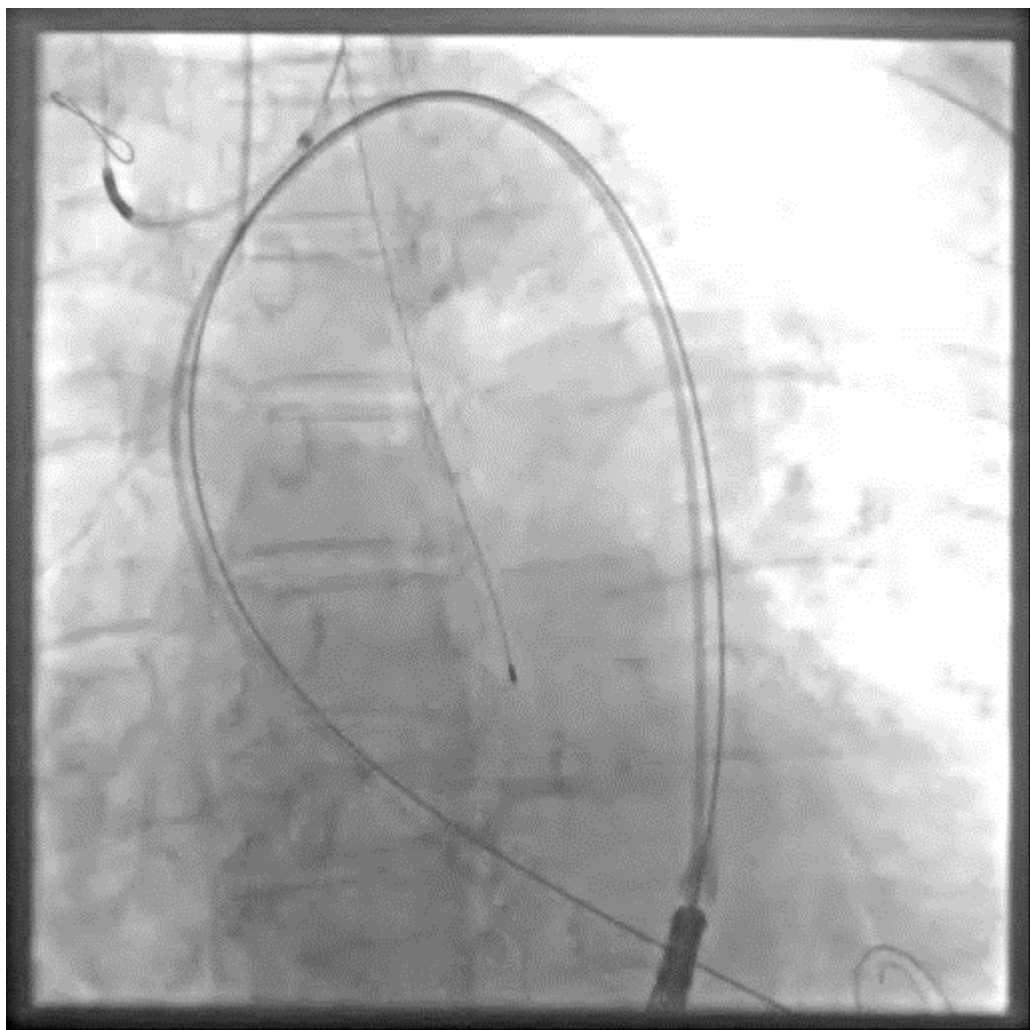
C COMMISSURAL (MIS)ALIGNMENT



B



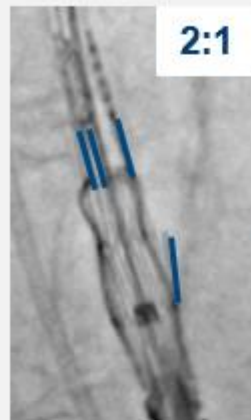
Accurate neo2 27mm



3 Cusp View (ACURATE neo2 marker at top of pigtail)

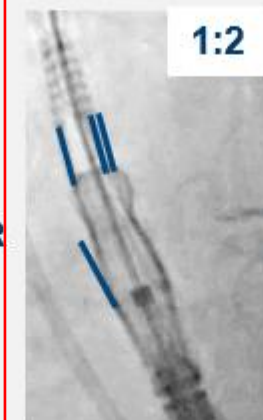


2:1



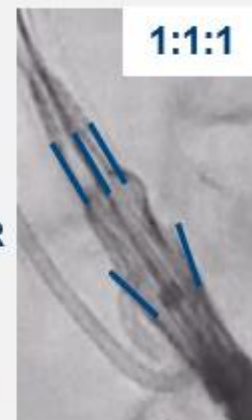
OR

1:2



OR

1:1:1



Rotate CW
away from operator

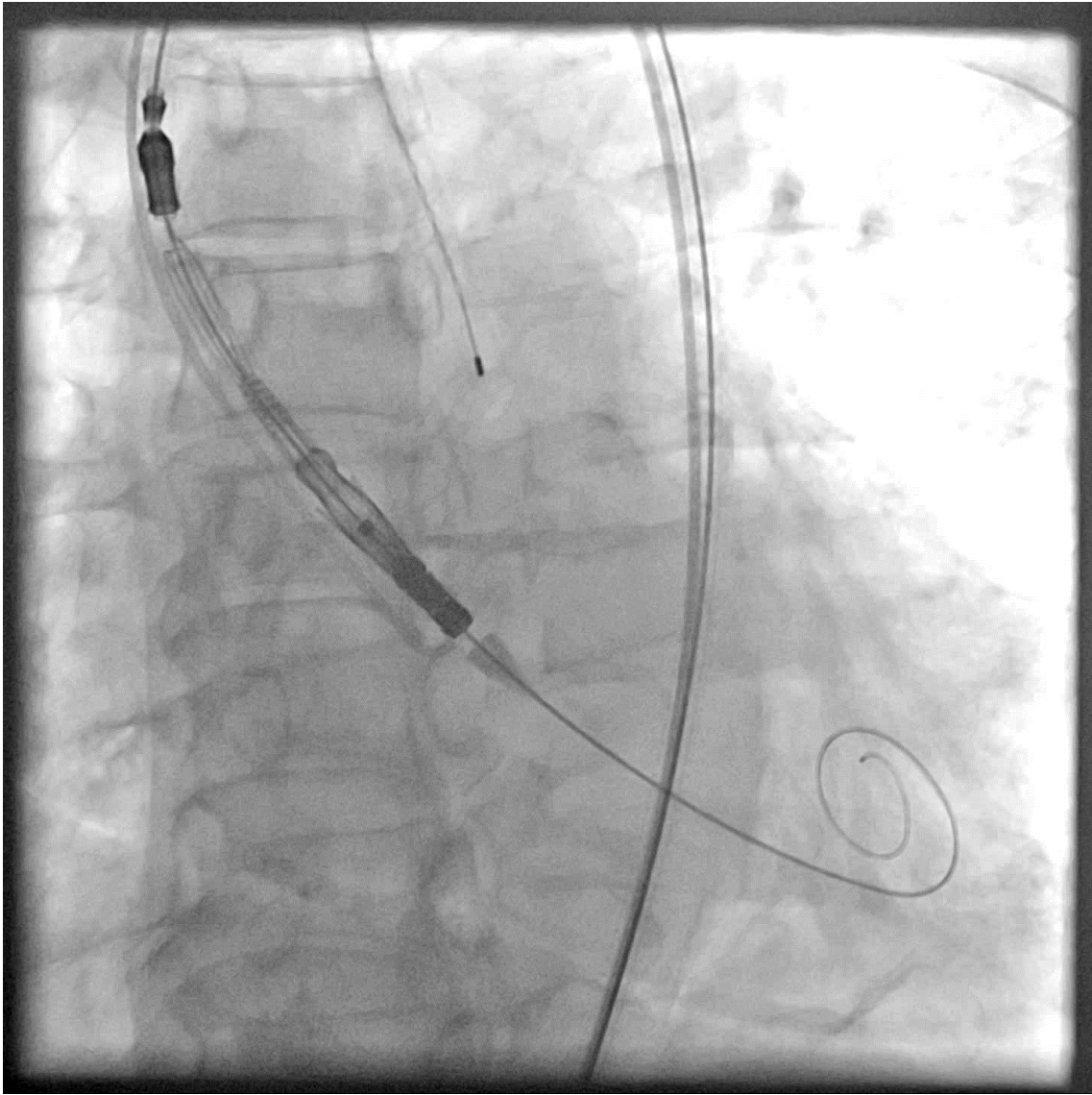


Rotate CCW
towards operator

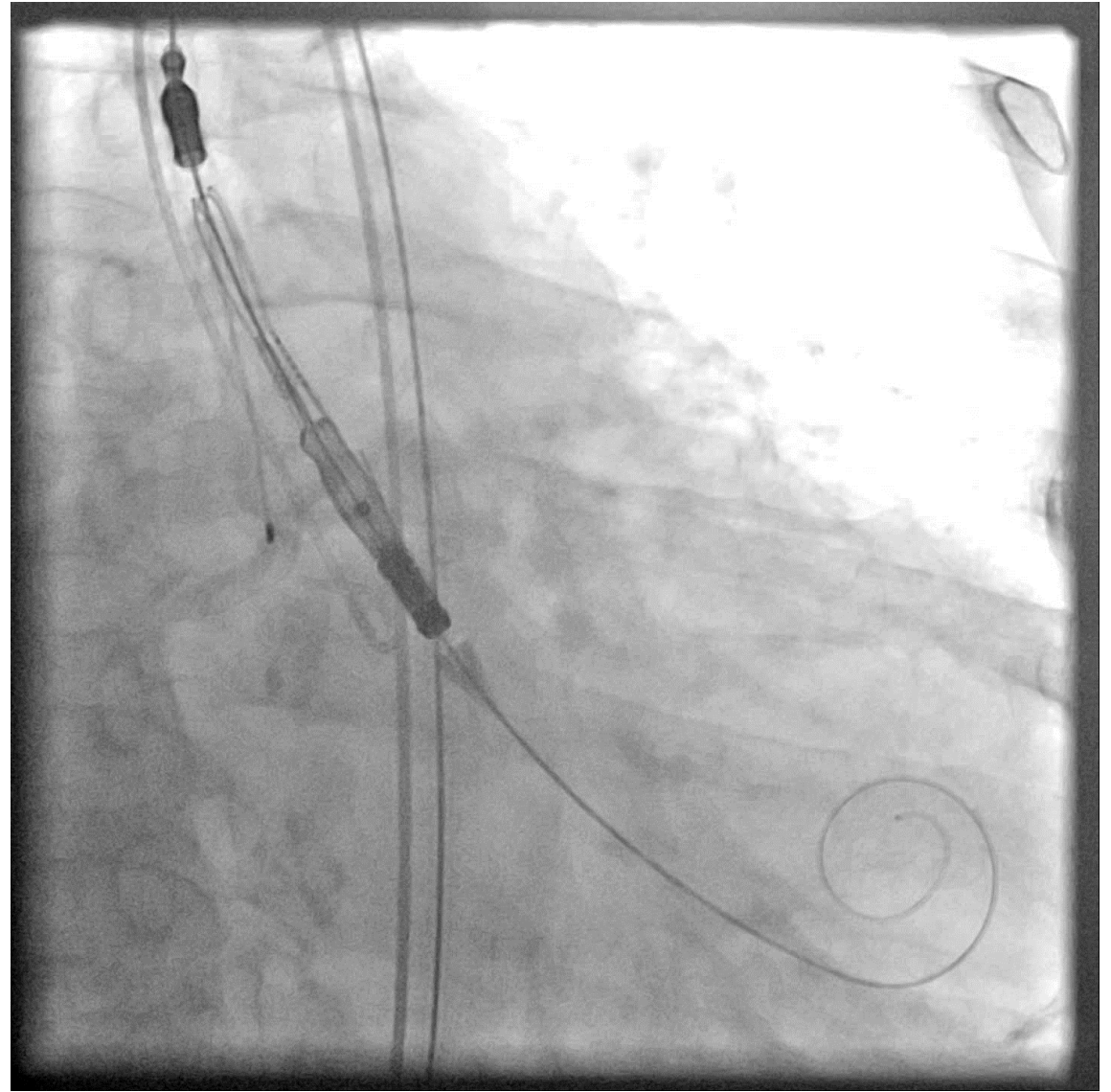


No rotation
Proceed to Step 3

Achieving Commissural Alignment: <1 minute

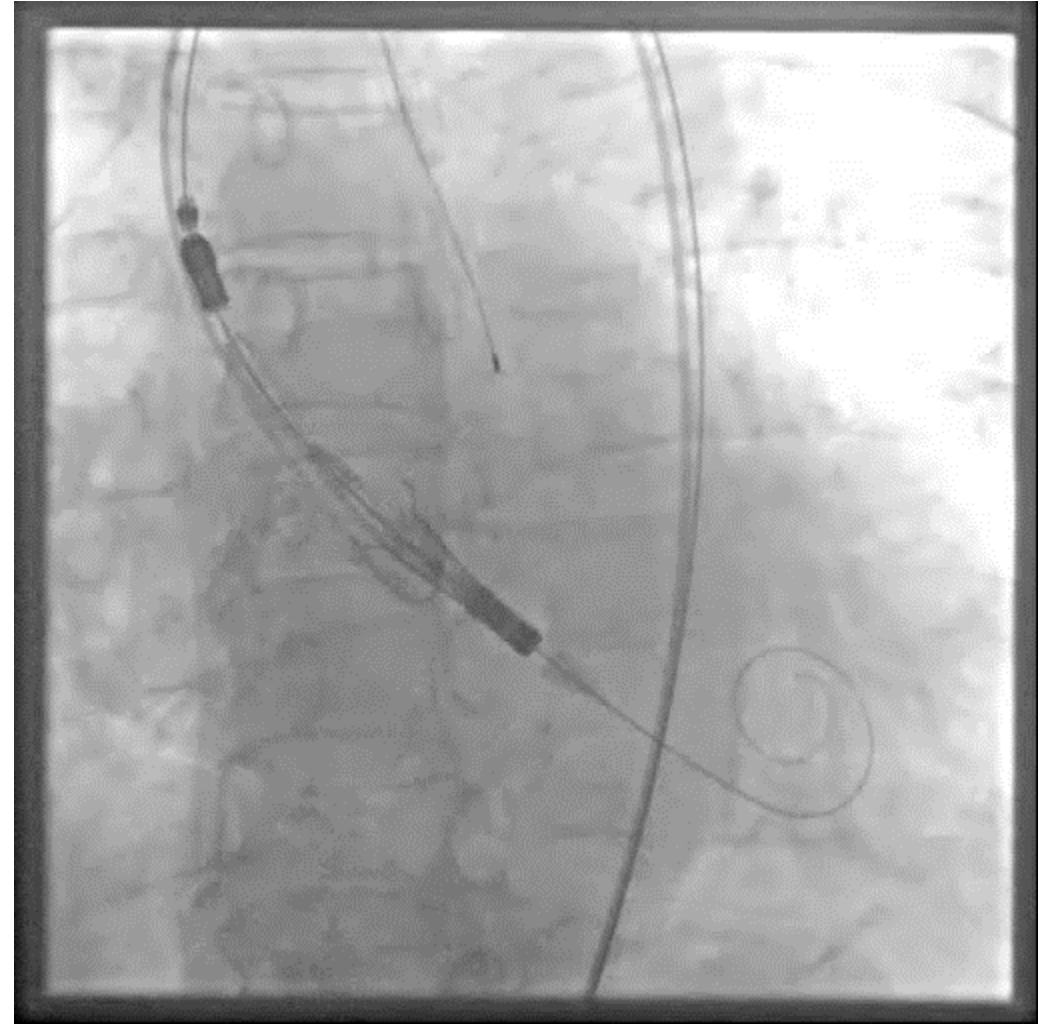
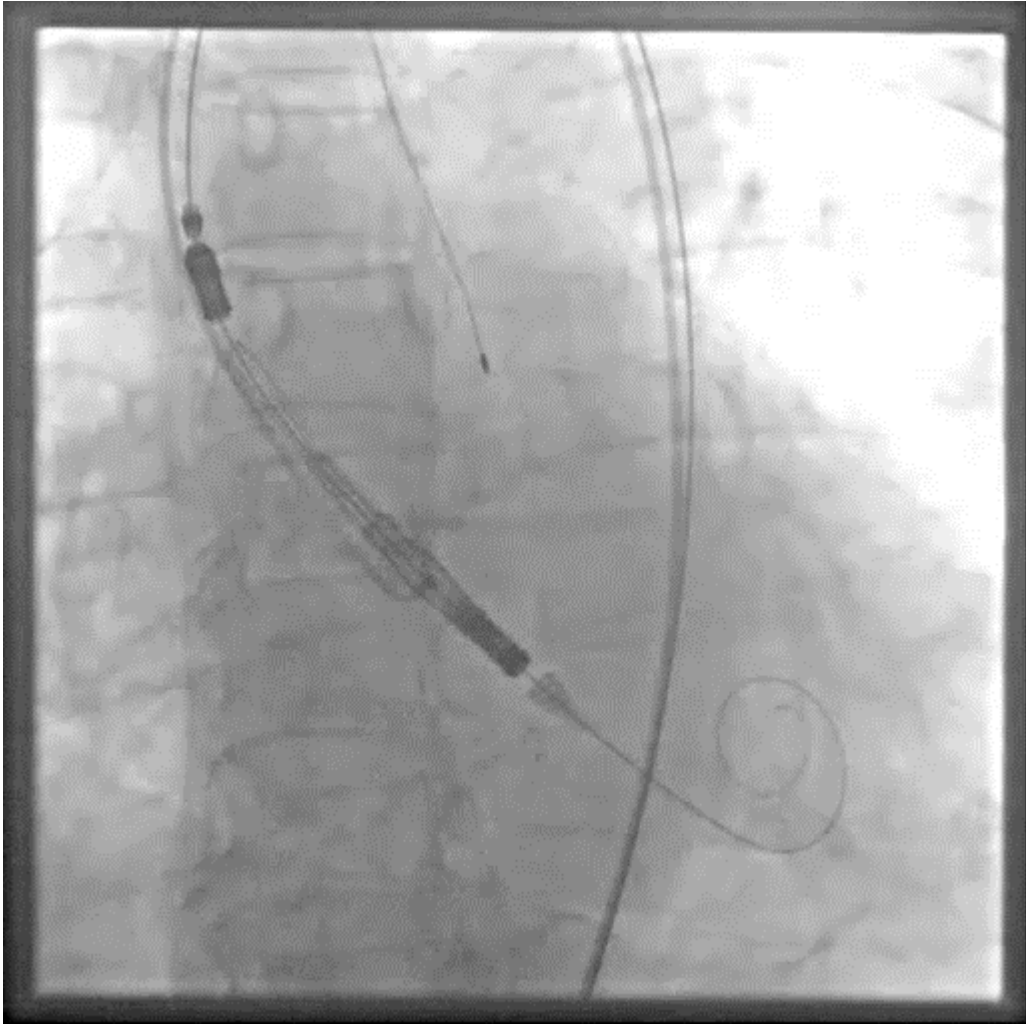


3 cusp view: 2 free cells symmetrically visible

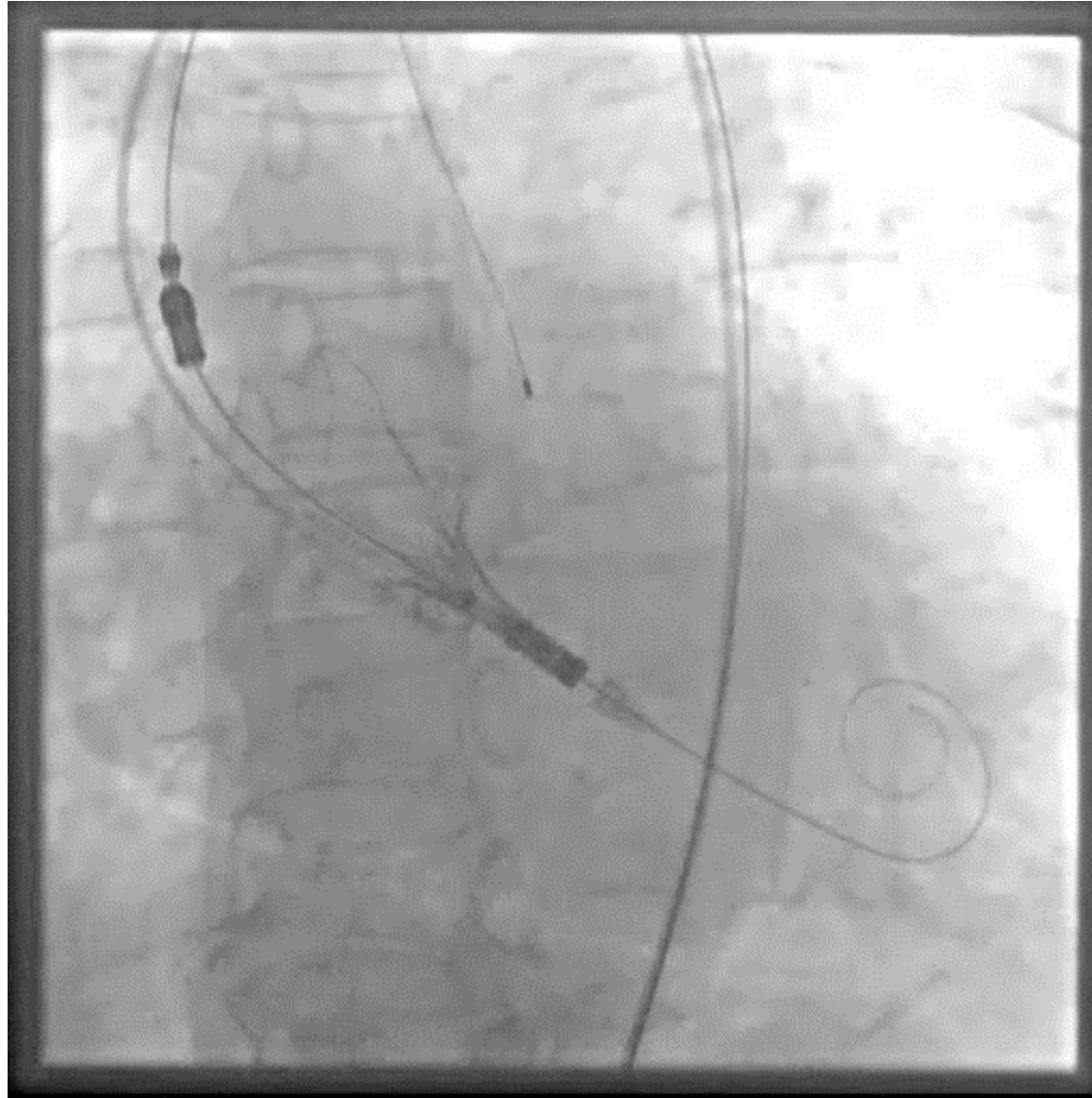


Cusp overlap view: 1 free cell on the inner curvature

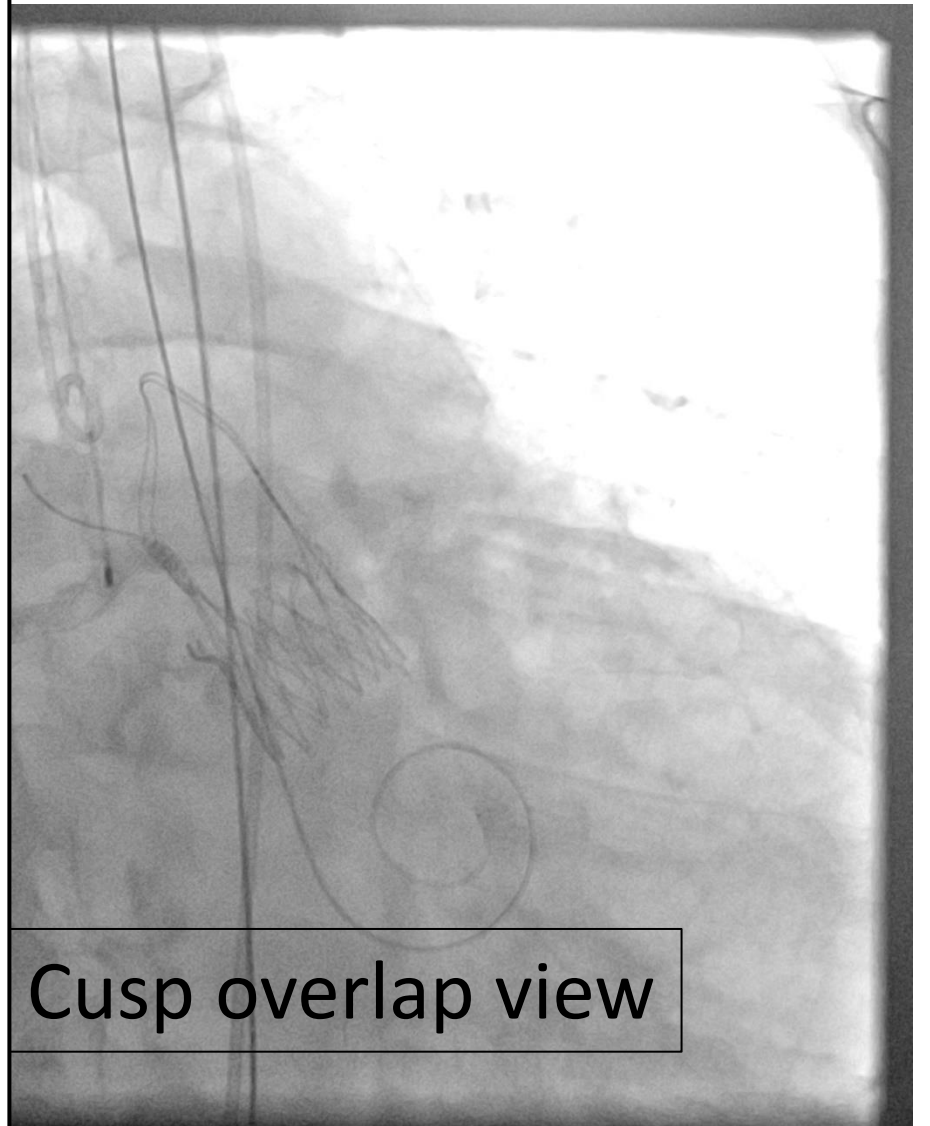
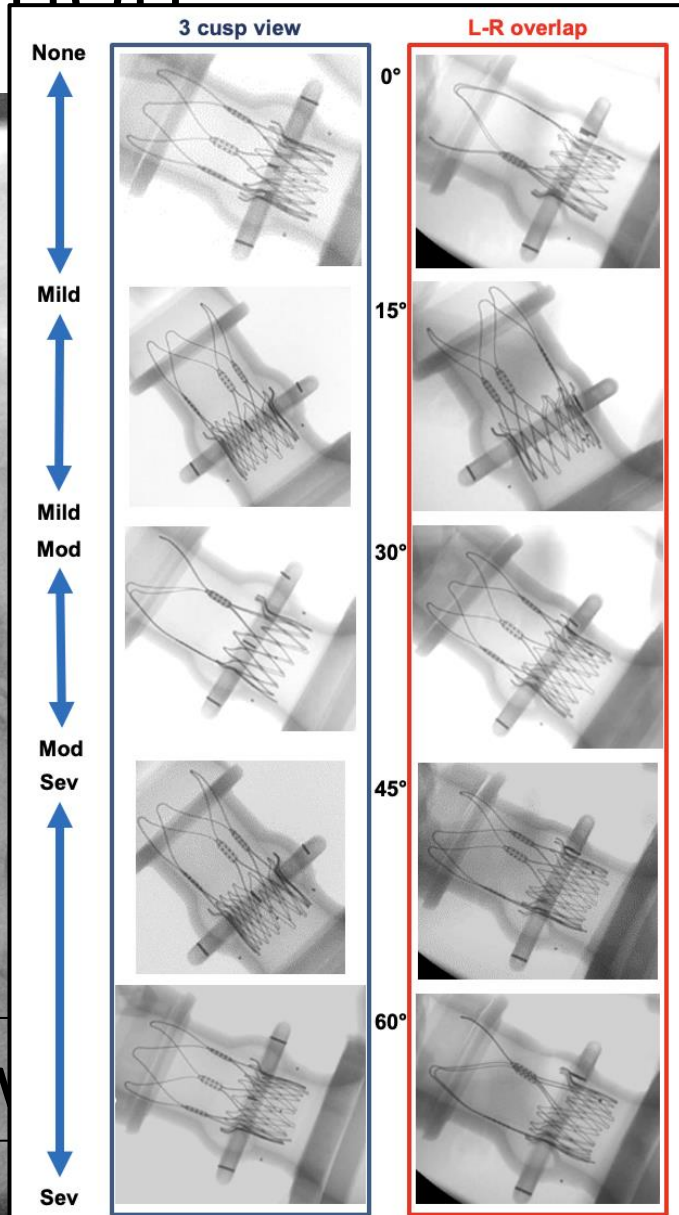
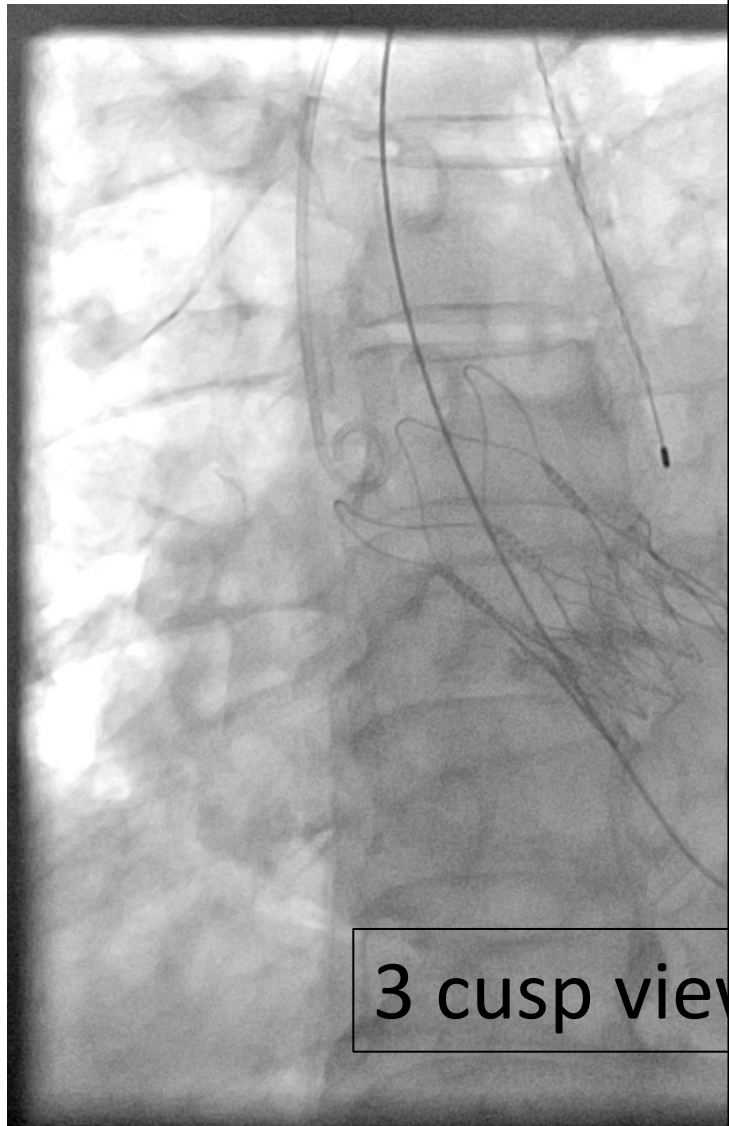
Classical ACURATE neo2 implantation : Step 1a and 1b



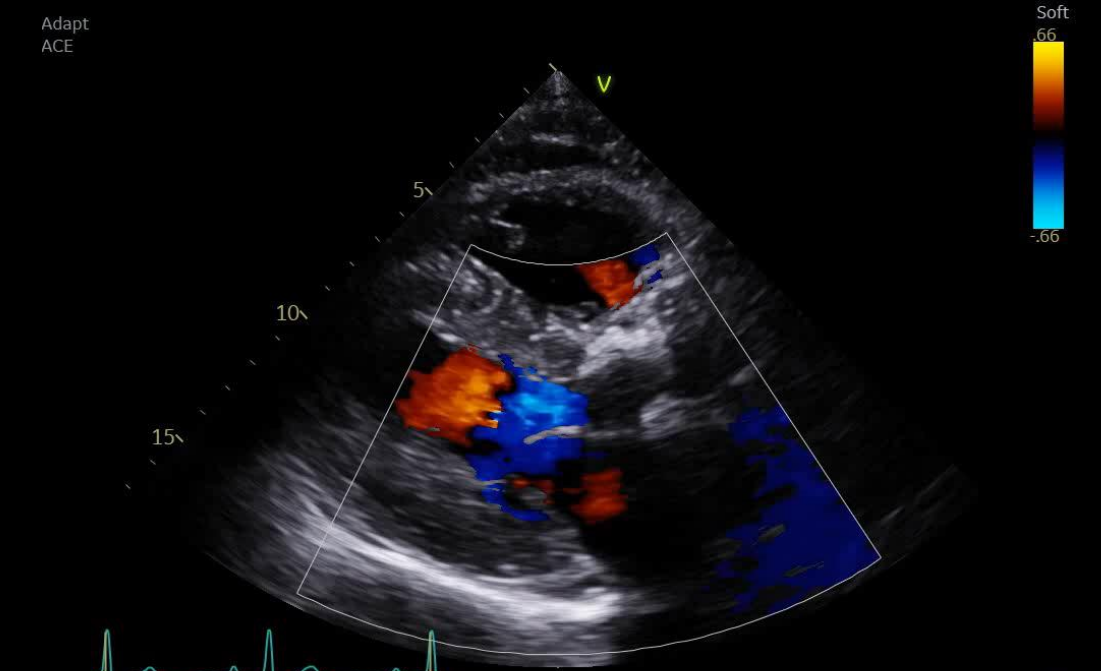
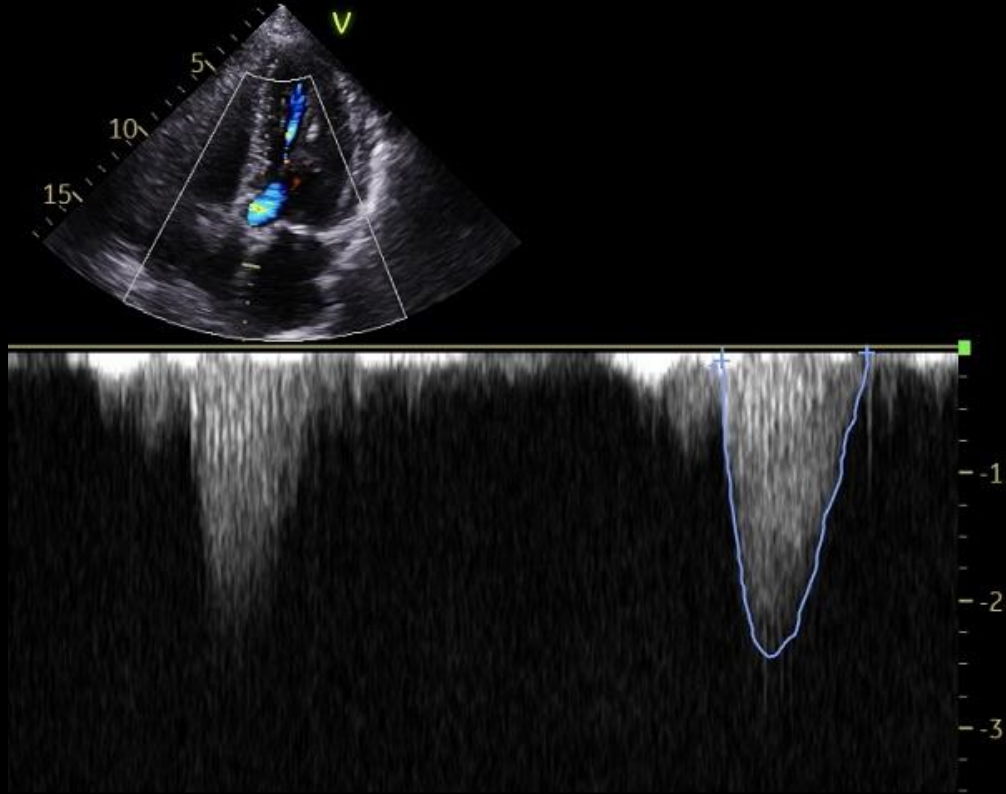
Classical ACURATE neo2 implantation: Step 2



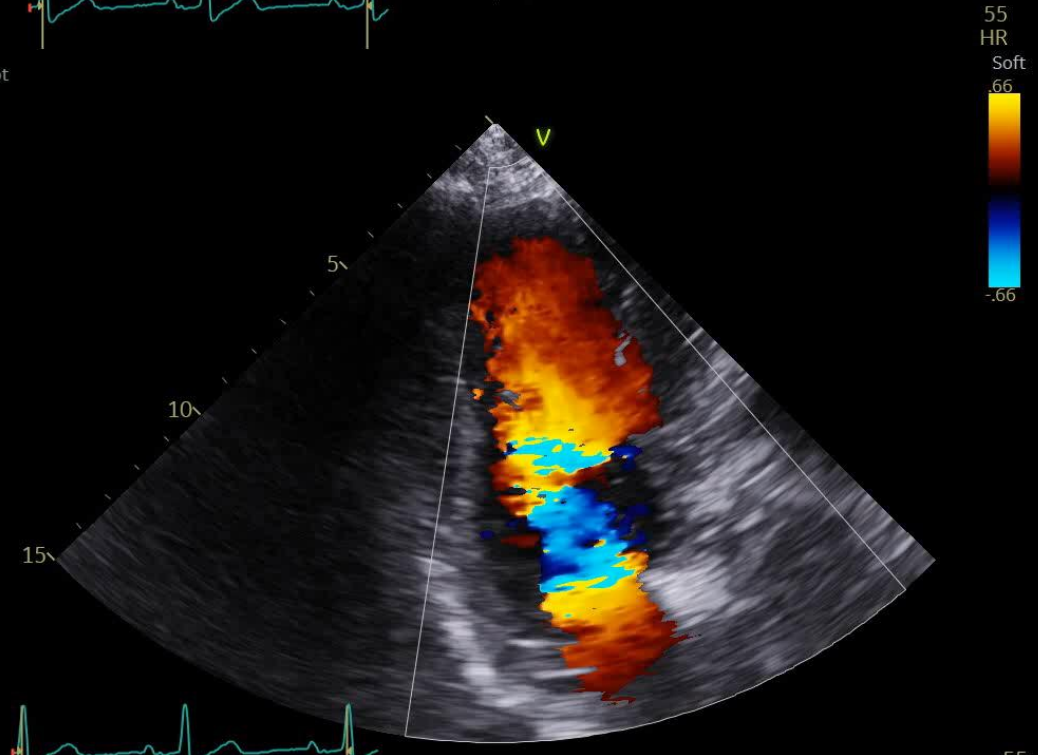
Final THV position



Post-TAVR TTE



Adapt
ACE

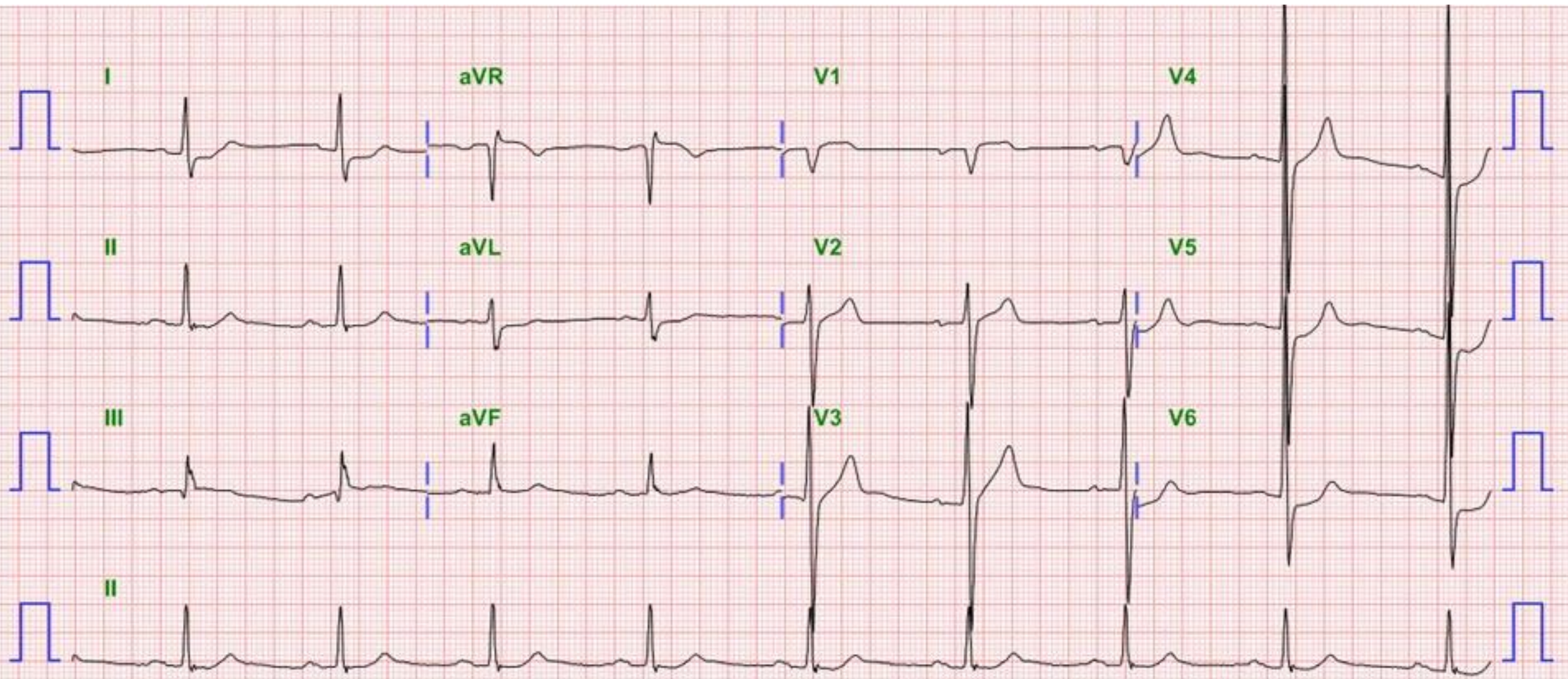


55
HR

55

Mean pressure gradient (mmHg) 59.6 -> 12.3
Peak velocity (m/sec) 4.85 -> 2.43
No visible PVL

Post-TAVR ECG



L
PA

Discharge home on POD #2

