고려대학교의료원
KOREA UNIVERSITY MEDICINE

ACURATE neo2 : Optimized Features and Benefits for TAVI patients in Korea

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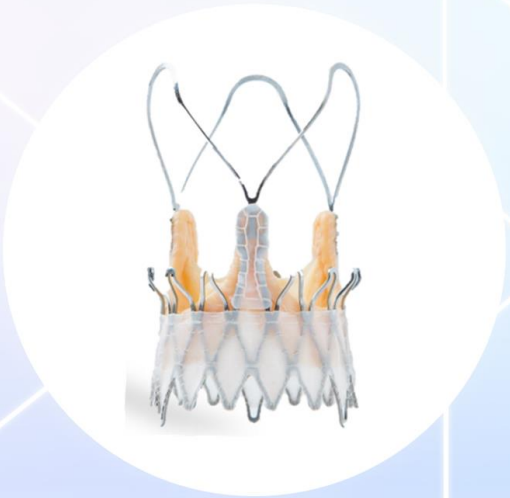
ENABLING
FUTURE MEDICINE

ACURATE Valve Platform

ACURATE™ Valve Platform



ACURATE™ TA

ACURATE™ *neo*

ACURATE™ *neo2*

Launched in August 2022

ACURATE Valve Platform

Design updates

Consistent valve features

Open stabilization arches

Supra-annular leaflets

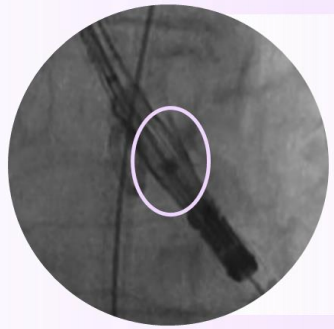
Upper crown

Lower crown

ACURATE *neo*™
Aortic Valve System

ACURATE *neo2*™
Aortic Valve System

New valve features



Radiopaque positioning marker

Expanded indication – including severe aortic stenosis patients of all risk strata as judged by heart team.

Extended (+60%) Active PVseal™ Sealing Skirt

The ACURATE neo2 valve

Valve Sizing

S – 23 mm | M – 25 mm | L – 27 mm

ACURATE neo2™ Aortic Valve			
Aortic annulus diameter*	21 mm ≤ annulus diameter ≤ 23 mm	23 mm < annulus diameter ≤ 25 mm	25 mm < annulus diameter ≤ 27 mm
Aortic annulus perimeter (mm)	66 mm ≤ annulus perimeter ≤ 72 mm	72 mm < annulus perimeter ≤ 79 mm	79 mm < annulus perimeter ≤ 85 mm

Delivery system

In small, out small.

14F iSLEEVE™ Expandable Introducer simplifies access with its low profile and smooth insertion.

14F **iSLEEVE™ Expandable Introducer**

Advanced Sealing
Triple-sealed hemostasis valve designed to minimize leakage

Smart Expansion
Responsive Tri-Fold Seams dynamically expand and contract with valve advancement

Smooth Procedures
State-of-the-art hydrophilic coating reduces insertion and withdrawl forces
Stability Layer increases stability and sealing

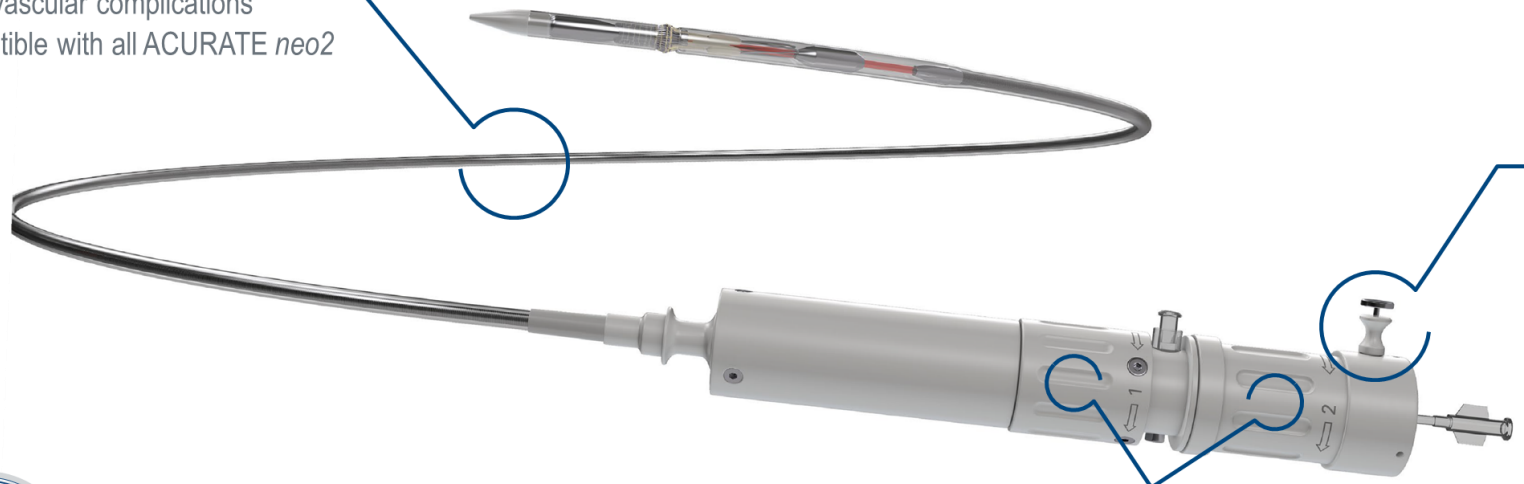
• Vessel indication ≥5.5mm

Delivery system

Transfemoral Delivery System

Flexible Delivery Catheter

- Designed to reduce risk of vascular complications
- One delivery system compatible with all ACURATE *neo2* valve sizes



Safety Button

To prevent premature implantation

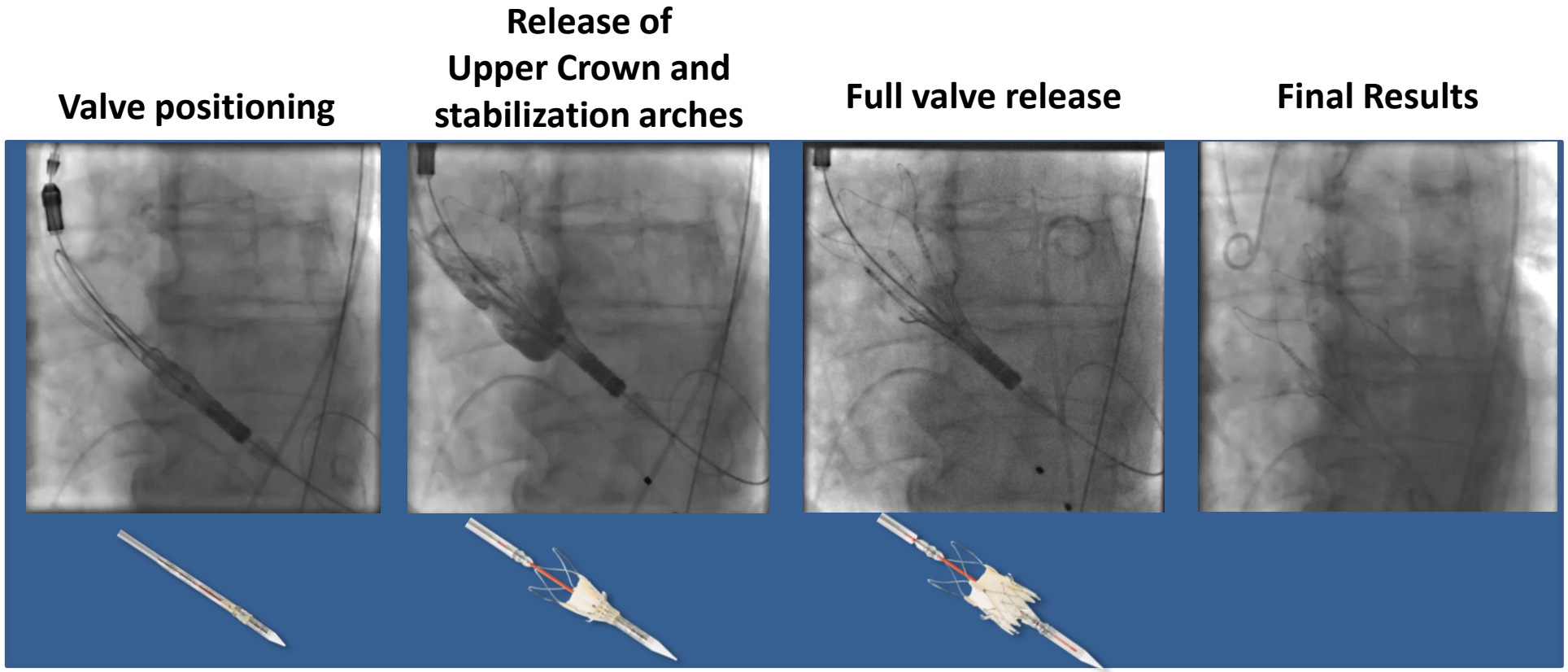
14F iSLEEVE™

Access small and complex vasculatures

Two Rotating Knobs

For intuitive step-by-step implantation

Sequence of implantation of ACURATE neo2 valve



Case study not necessarily representative of all cases. Results in other cases may vary.

Delivery system

Smooth deliverability

Expect uncompromised deliverability even in small and tortuous anatomies with the low-profile iSLEEVE™* and intuitive, top-down deployment of ACURATE *neo2*™

Superior device success among patients with horizontal aortas

91.2% ACURATE *neo2* Valve[1] **vs.** **86.6%** Evolut™ R/PRO

(P < 0.002)

ACURATE *neo2* Valve tracking and deployment in tortuous anatomy

*The iSLEEVE Expandable Introducer Sheath is indicated for vessels ≥ 5.5 mm.

1. Gallo F, Gallone G, Kim W-K, et al. Horizontal aorta in transcatheter self-expanding valves: Insights from the HORSE International Multicentre Registry. *Circ Cardiovasc Interv*. 2021;14(9):e010641.

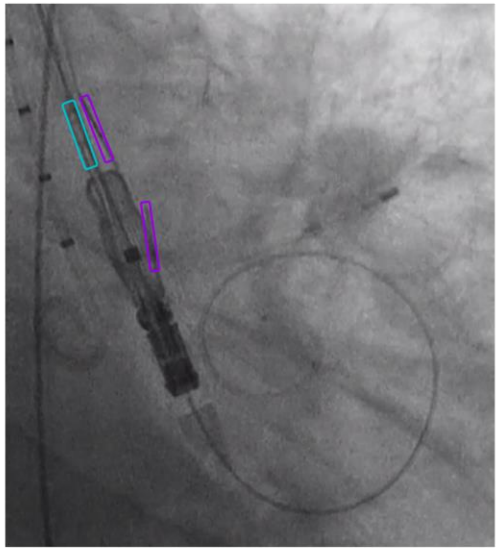
Video source: https://www.youtube.com/watch?v=TAEVPjx8uUU.

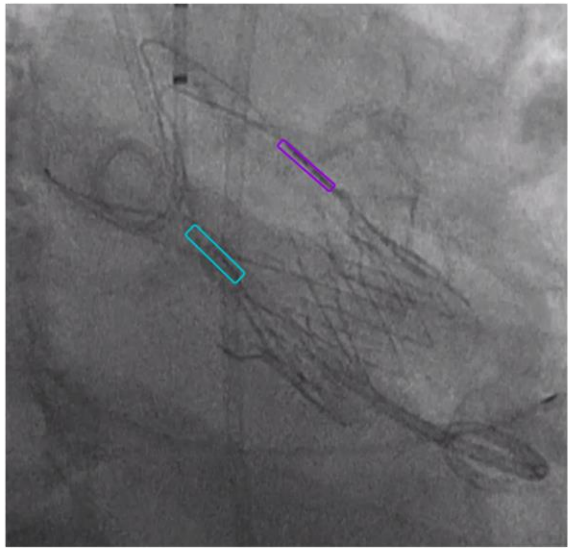
Delivery system

Predictable alignment

Design that delivers best-in-class commissural alignment

Easy-to-rotate delivery catheter with three radiopaque commissural posts enables easy, predictable commissural alignment.[1,2]





100%

Freedom from moderate or severe commissural misalignment[1]

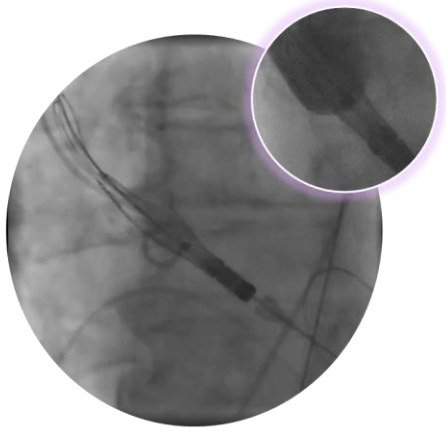
92s

Average commissural alignment time[2]

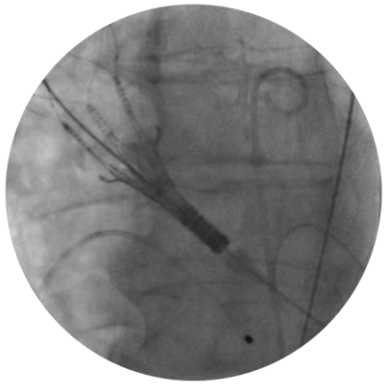
1. Bieliauskas G, Wong I, Bajoras V, et al. Patient-specific implantation technique to obtain neo-commissural alignment with self-expanding THVs. *JACC Cardiovasc Interv*. 2021;14(19):2097–2108.
2. Meduri et al., presented at EuroPCR 2022.

Delivery system

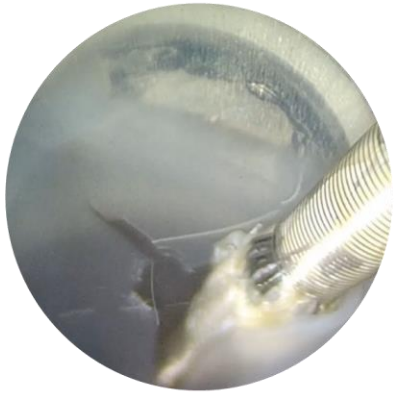
Precise positioning



Upper crown and stabilization arches release



Full valve release



No annular flow restriction

Easy-to-spot radiopaque positioning marker delivers short procedures and high success rates[1,2]

98.4% procedural success

3.9min. deployment time

ACURATE *neo2*™ Aortic Valve System unique top-down deployment[1]

Self-alignment of the valve within the native annulus with hemodynamic stability throughout the procedure

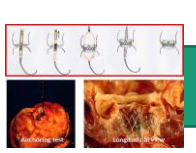
1. Kim W., et al; Clinical outcomes of the ACURATE neo2 transcatheter heart valve: a prospective, multicenter, observational, post-market surveillance study, EuroIntervention 2022. DOI: 10.4244/EIJ-D-22-00914
2. Möllmann H, Holzhey DM, Hilker M, et al. The ACURATE *neo2* valve system for transcatheter aortic valve implantation: 30-day and 1-year outcomes. *Clin Res Cardiol*. 2021;110(12):1912–192.

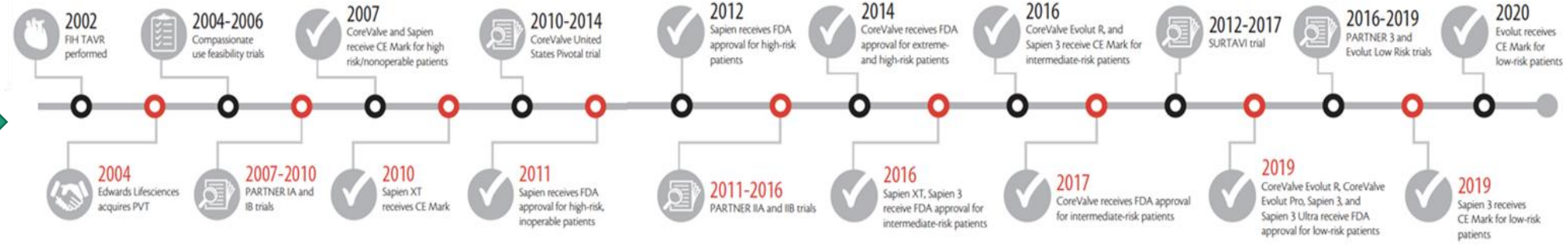
What is optimized Feature and benefit for TAVI?

The Evolution of TAVR

Next Round

High risk → *intermediate risk* → *low risk*





Inoperable
High Risk

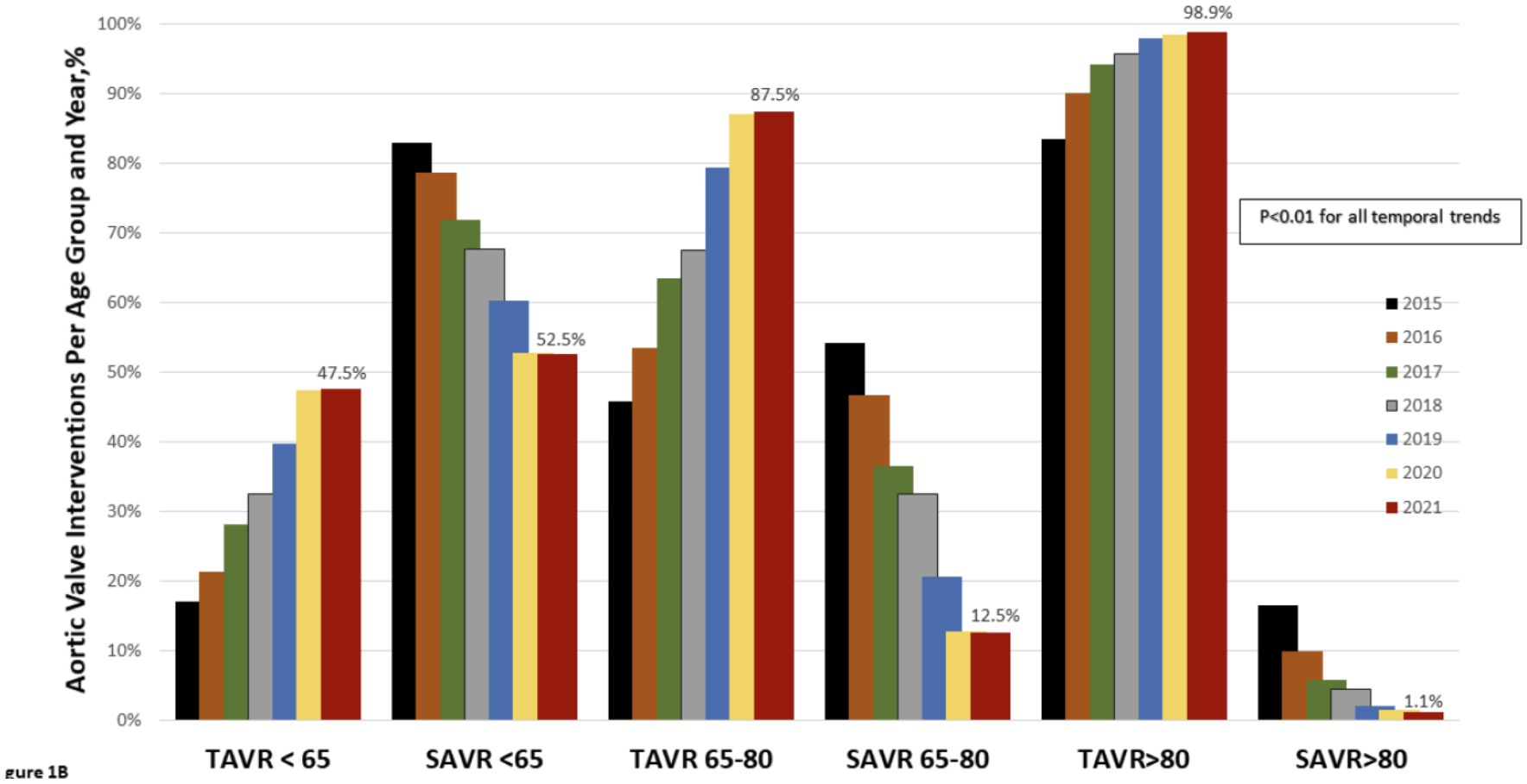
83-84 yrs

Low Risk

73-74 yrs

Trend of Isolated AVR in US

47.5% of <65 YO, 87.5% of 65-80 YO, 98.9% of >80 YO Underwent TAVR !!



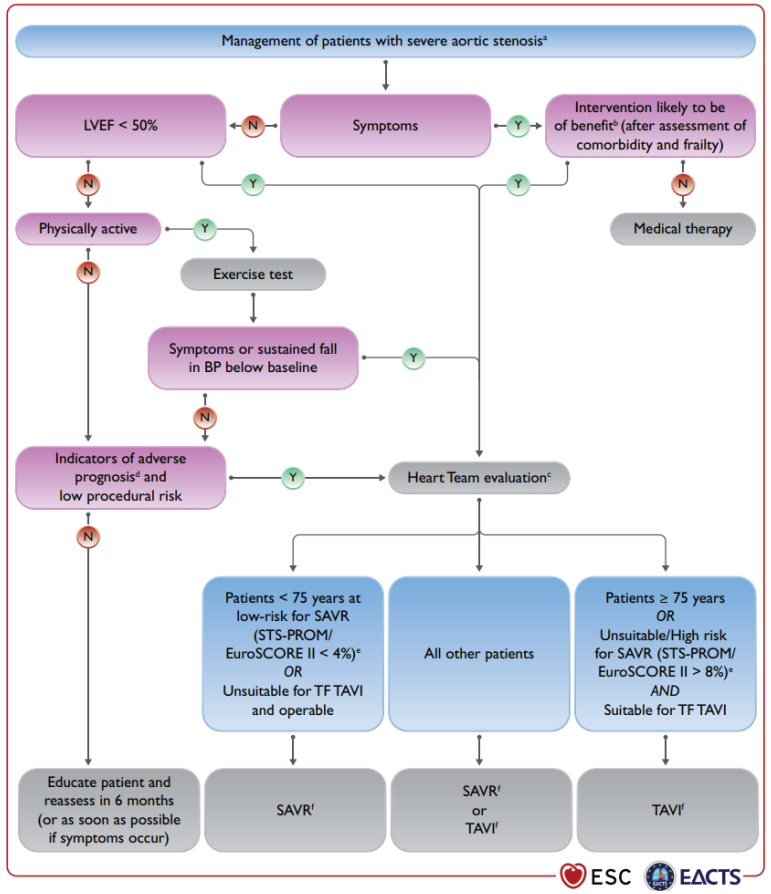
gure 1B

Sharma T et al. J Am Coll Cardiol. 2022 Sep 8:S0735-1097(22)06756-0.

Recent Guidelines of TAVI

2021 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by the Task Force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)

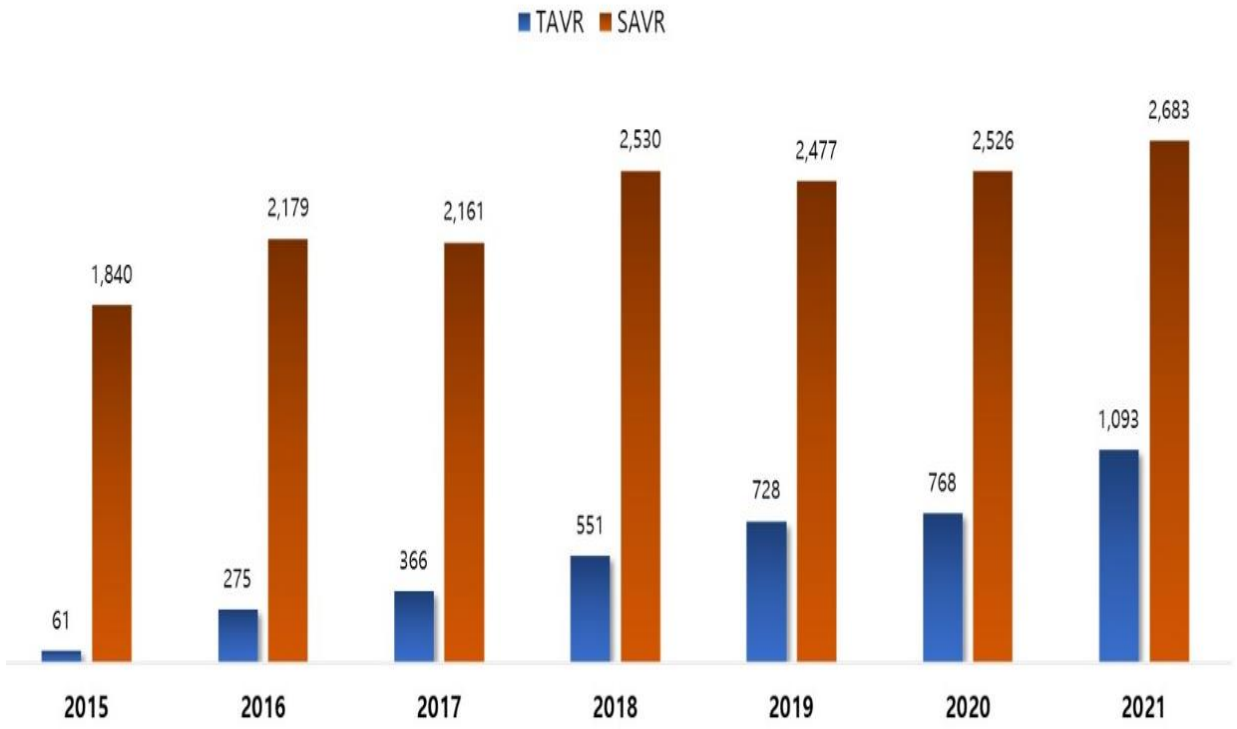


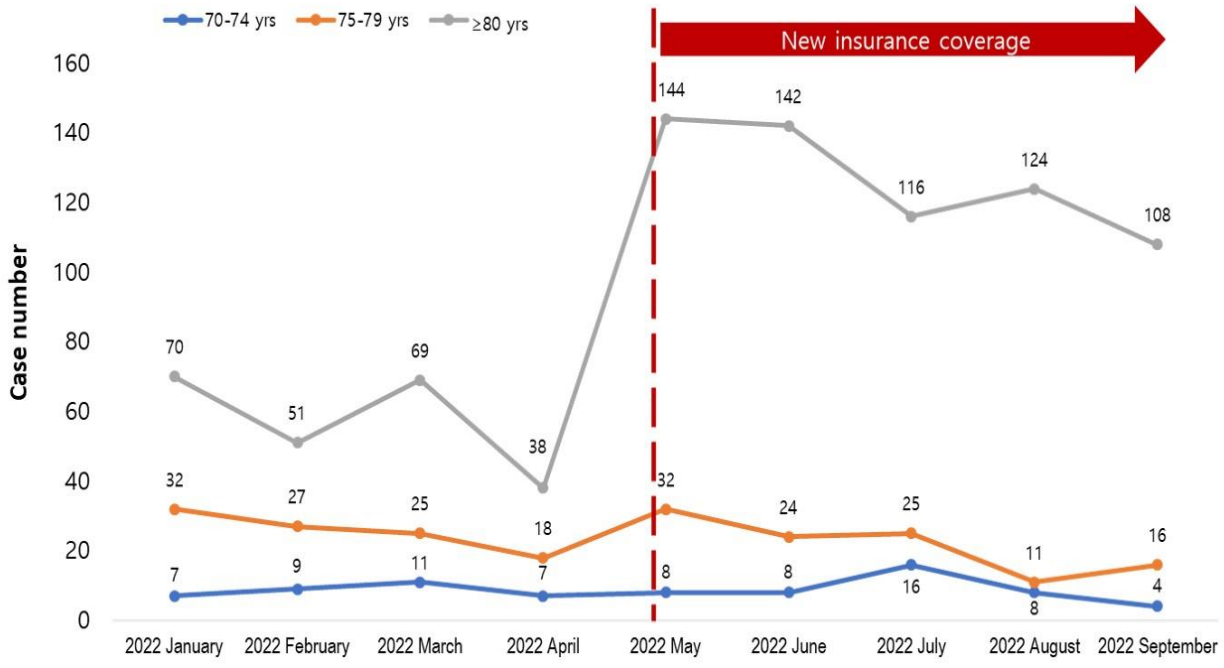
	Previous guidelines		Current guidelines	
Revised	SAVR is recommended in patients at low surgical risk (STS or EuroSCORE II <4% or logistic EuroSCORE I <10%, and no other risk factors not included in these scores, such as frailty, porcelain aorta, sequelae of chest radiation).	I	SAVR is recommended in younger patients who are low risk for surgery (<75 years and STS-PROM/ EuroSCORE II <4%) or in patients who are operable and unsuitable for transfemoral TAVI.	I
Revised	TAVI is recommended in patients who are not suitable for SAVR as assessed by the Heart Team.	I	TAVI is recommended in older patients (≥75 years), or in those who are high-risk (STS-PROM/ EuroSCORE II >8%) or unsuitable for surgery.	I

Who should undergo TAVR? (Surgical High Risk) → **Who should undergo SAVR? (Anatomic High Risk)**

Vahanian et al. European Heart Journal (2022) 43, 561–632

Trend of Isolated AVR in Korea





Journal of Cardiovascular Intervention (2023) In press

Optimized Feature and benefit for TAVI

PROCEDURAL
SUCCESS METRICS

- Mortality & Stroke
- Quality of Life
- Conduction Disturbance (PPI)

Higher risk + **Lower Risk**

AGE

80+	65+, CAD

ANATOMY

Tri-leaflet	More Bicuspid

ACTIVITY

Low	High(er)

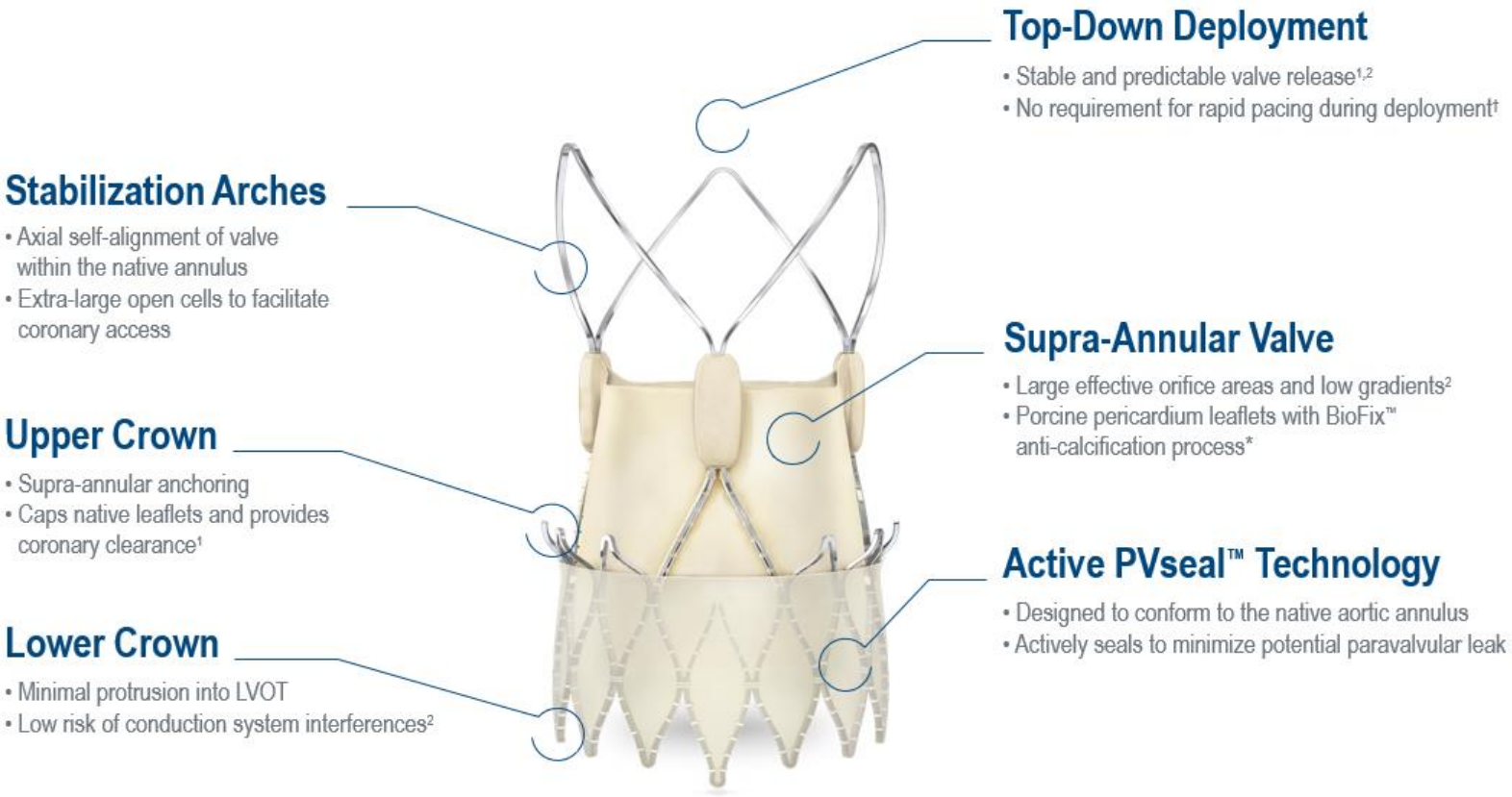
LIFETIME
MANAGEMENT METRICS

- Hemodynamics & PPM
- Durability < Life Expectancy
- Coronary Access (PCI) & TAV-in-TAV

Courtesy of Dr. Kang

The ACURATE neo2 valve

Optimized Feature and benefit for TAVI



- Conduction disorders
- Hemodynamics
- Paravalvular leak
- Coronary access
- Durability

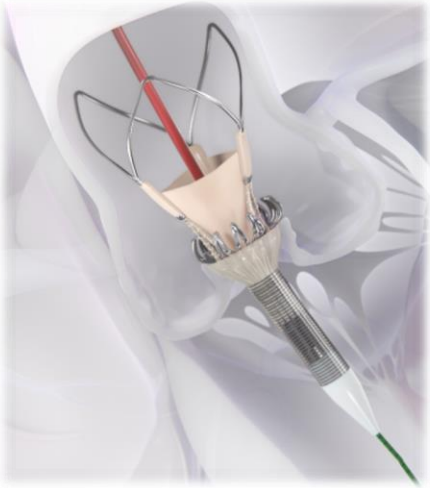
Conduction disorders

Best-in-class PPI

Lower your patients' pacemaker risk

- Patients who receive PPI after TAVI experience higher mortality and rehospitalization risk[1]
- With top-down deployment and upper- and lower-crown anchoring, the ACURATE *neo2*™ Aortic Valve System minimizes LVOT protrusion

6%
new permanent pacemaker rate*[2]
***in hospital**



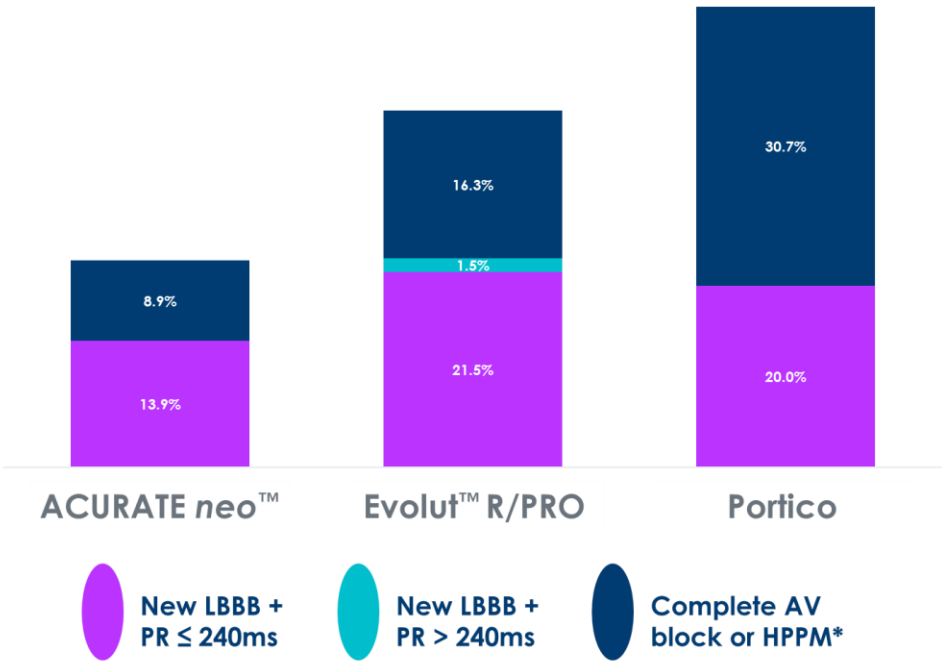
1. Pompeu M, et al. Late outcomes of permanent pacemaker implantation after TAVR: Meta-analysis of reconstructed time-to-event data, *JSCAI*. 2022. doi:https://doi.org/10.1016/j.jscai.2022.100434.
2. Rück A. Early *neo2* Registry. Full Core-lab Results of TAVI with the New ACURATE *neo2* Valve. TVT Congress. 2021.

ACURATE *neo2*™
Aortic Valve System

Trusted Outcomes

Conduction disorders

Best-in-class PPI



Reducing conduction injury matters

- Persistent LBBB is a known contributor to increased TAVI patient mortality[1]
- ACURATE is associated with a **50% decrease** in TAVI patient conduction injury at discharge vs. other self-expanding valves[2]

*HPPM = Hospital Permanent Pacemaker

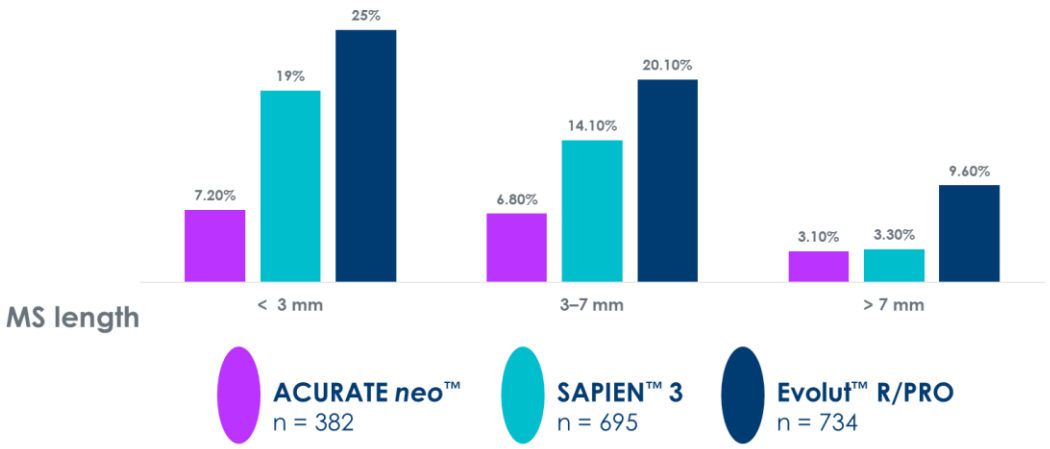
1. Tsushima T, Main A, Al Kindi SC, et al. Risk Stratification of new persistent left bundle branch block after transcatheter aortic valve implantation. *Am J Cardiol*. 2022.
2. Castro-Mejía AF. Development of atrioventricular and intraventricular conduction disturbances in patients undergoing transcatheter aortic valve replacement with new generation self-expanding valves: A real world multicenter analysis. *J Cardiol*. 2022.

Conduction disorders

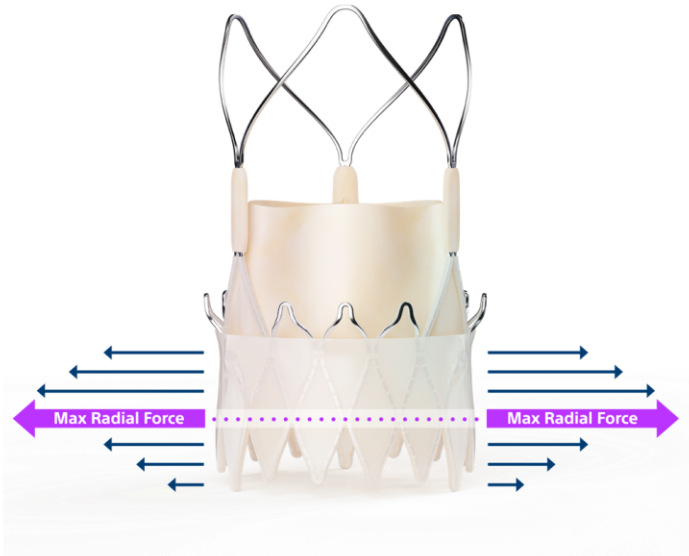
Best-in-class PPI

ACURATE *neo2*™ Aortic Valve System demonstrates the lowest PPI rates for patients at the highest risk of conduction injury[1]

Post-TAVI pacemaker implantation rate by THV type and membranous-septum length (n = 1811)



Optimized radial outward force distribution minimizes conduction system injury[1]



1. Thijmen W. Hokken et al., The INTERSECT Registry 2022.

ACURATE *neo2*
Aortic Valve System

Trusted Outcomes

Hemodynamics

Single-digit gradients

Supra-annular valve design maximizes leaflet opening for single-digit gradients and large EOAs[1]

Single-digit gradients[2]

8.0 mmHg

Large EOAs[1]

1.7 cm^2

1. Möllmann H, Holzhey DM, Hilker M, et al. The ACURATE *neo2* Valve System for transcatheter aortic valve implantation: 30-day and 1-year outcomes. *Clin Res Cardiol*. 2021;110:1912–1920.
2. Early *neo2* Registry. Full Core-Lab Results of TAVI with the New ACURATE *neo2* Valve. TVT Congress. Presenter: Andreas Rück. July 20, 2021.

ACURATE *neo2*®
Aortic Valve System

Trusted Outcomes

Hemodynamics

Single-digit gradients

Protect patients' futures[1]

- Severe PPM is associated with increased mortality post-TAVR[2]
- Minimize the risk of prosthesis-patient mismatch, even in patients with small annuli

Reduced rates of elevated gradients and severe PPM vs. SAPIEN™ 3 Ultra[3]

ACURATE *neo2*™ Aortic Valve System	SAPIEN™ 3 Ultra
Elevated gradients*	
$p < 0.001$	
2.4%	**7.7%**
Severe PPM	
2.9%	**15.0%**

*(≥ 20mmHg)

1. Pibarot P, Dumesnil JG. Prosthesis-patient mismatch: Definition, clinical impact, and prevention. *Heart*. August 2006;92(8):1022-1029.
2. Mompeu M. Impact of Prosthesis-patient mismatch after TAVR: *JACC* CI Sep 16, 2022.
3. Pellegrini C. ACURATE *neo2* versus SAPIEN 3 Ultra. Interventions for valvular disease and heart failure.

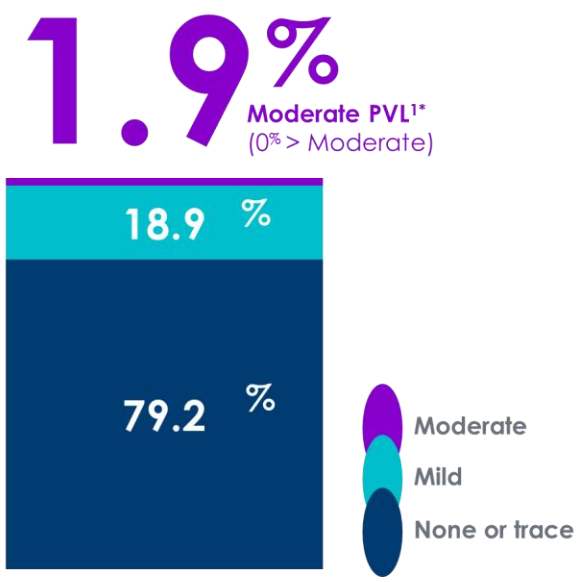
ACURATE *neo2*
Aortic Valve System

Trusted Outcomes

Paravalvular leak

Advanced PVL performance

Protect against PVL with the ACURATE *neo2*™ Aortic Valve System's advanced sealing skirt.



Inner and outer ACTIVE PVseal™ extends the full waist of the ACURATE *neo2* Valve, maximizing sealing efficacy

* At 30-days, Echocardiographic and CT imaging Independently core lab adjudicated

1. Kim W., et al; Clinical outcomes of the ACURATE neo2 transcatheter heart valve: a prospective, multicenter, observational, post-market surveillance study, EuroIntervention 2022. DOI: 10.4244/EIJ-D-22-00914

ACURATE *neo2*
Aortic Valve System

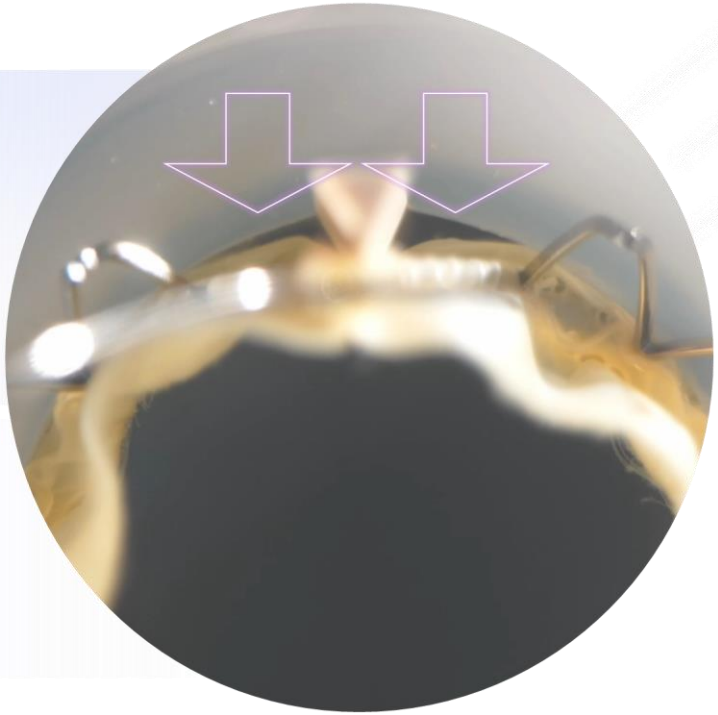
Trusted Outcomes

Paravalvular leak

Advanced PVL performance

ACTIVE PVseal™ is designed to conform to anatomy during each cardiac cycle.**

14–16 mm
ACTIVE PVseal height**



*Video from hydrodynamic bench simulation, not representative of procedural outcomes
**ACTIVE PVseal height ranges from 14-16 mm across ACURATE *neo2* Small, Medium and Large Valve Sizes (Data on file at BSC)

ACURATE *neo2*
Aortic Valve System

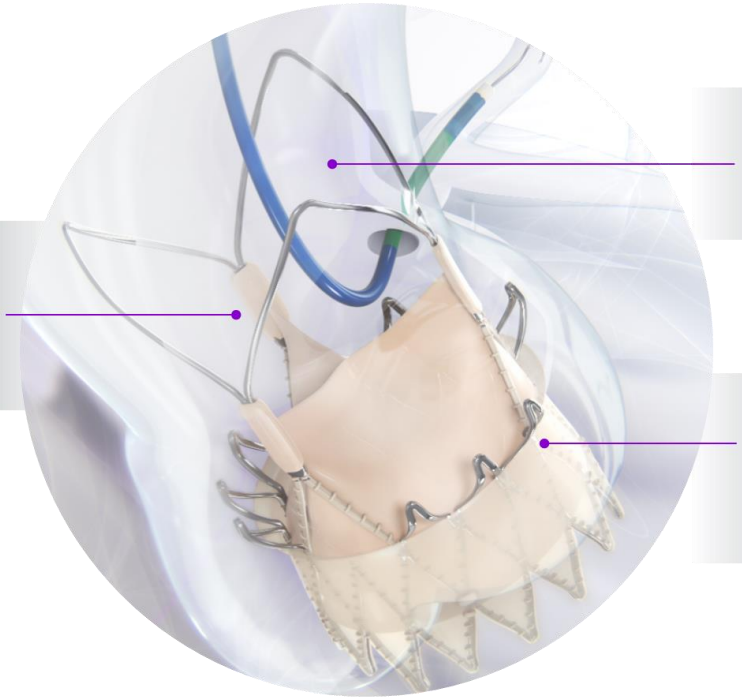
Trusted Outcomes

Coronary access

Lower-risk TAVI requires preserved future access.[1] STEMI following TAVI resulted in[2]:

- **4x higher PCI failure rate**
- **33% increased mortality rate**

100%	82%	99%
ACURATE *neo*™ Valve platform	**Evolut™ R/PRO**	**SAPIEN™**
100% successful coronary cannulation n = 72	82% successful coronary cannulation n = 123	99% successful coronary cannulation n = 96



The ACURATE *neo2* design is associated with favorable post-TAVI coronary access[1]

1. Reobtain Coronary Ostia Cannulation Beyond Transcatheter Aortic Valve Stent (RE-ACCESS); NCT04026204. J Am Coll Cardiol Intv. 2020.
2. Faroux L, et al. ST-Segment Elevation Myocardial Infarction Following Transcatheter Aortic Valve Replacement. "https://www.jacc.org/journal/jacc" J Am. Coll. Cardiol. 2021 May, 77 (17) 2187 -2199.

Coronary access

The largest accessible stent cell area[1]

	ACURATE *neo2*™ Aortic Valve System Small	SAPIEN™ 3 23 mm	Evolut™ R 26 mm	NAVITOR 29 mm[2]
Area	489.0 mm^2	32.9 mm^2	15.7 mm^2	68.7 mm^2
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.

ACURATE *neo2*™ Aortic Valve System

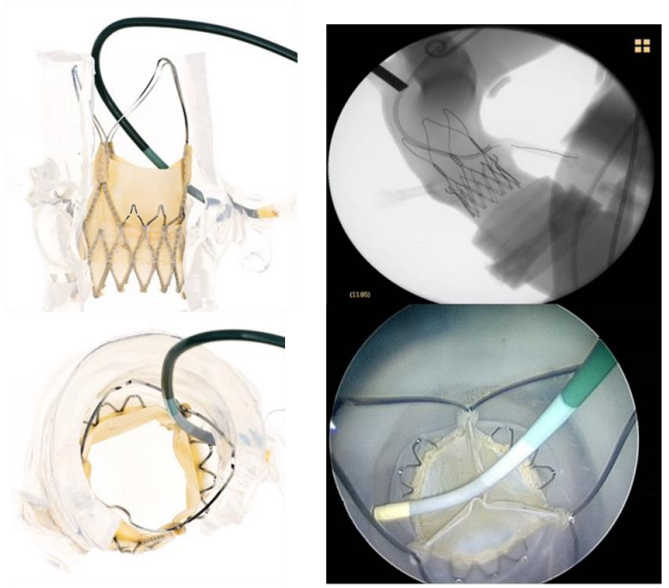
Coronary access

Open upper stabilization arches allow for unique coronary access techniques.

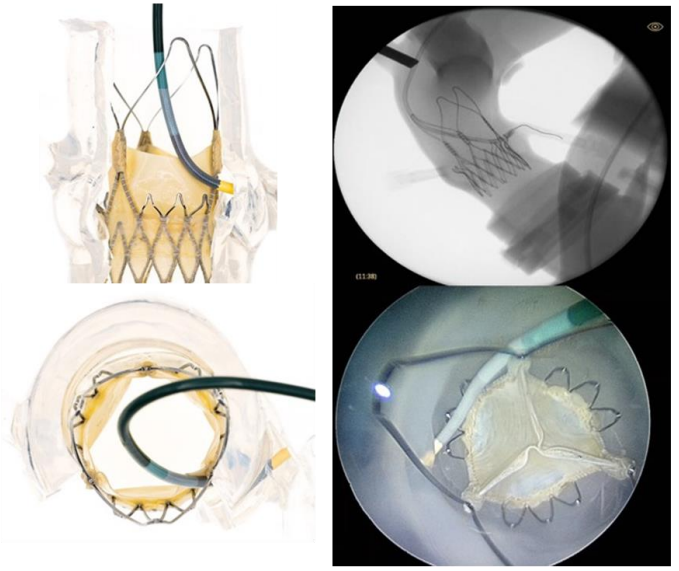
Split-level design

Open upper frame

Stent body



Open stabilization arches allow sufficient space to manipulate catheter



Catheter able to bypass commissural posts

ACURATE *neo2*™
Aortic Valve System

Unrestricted Design

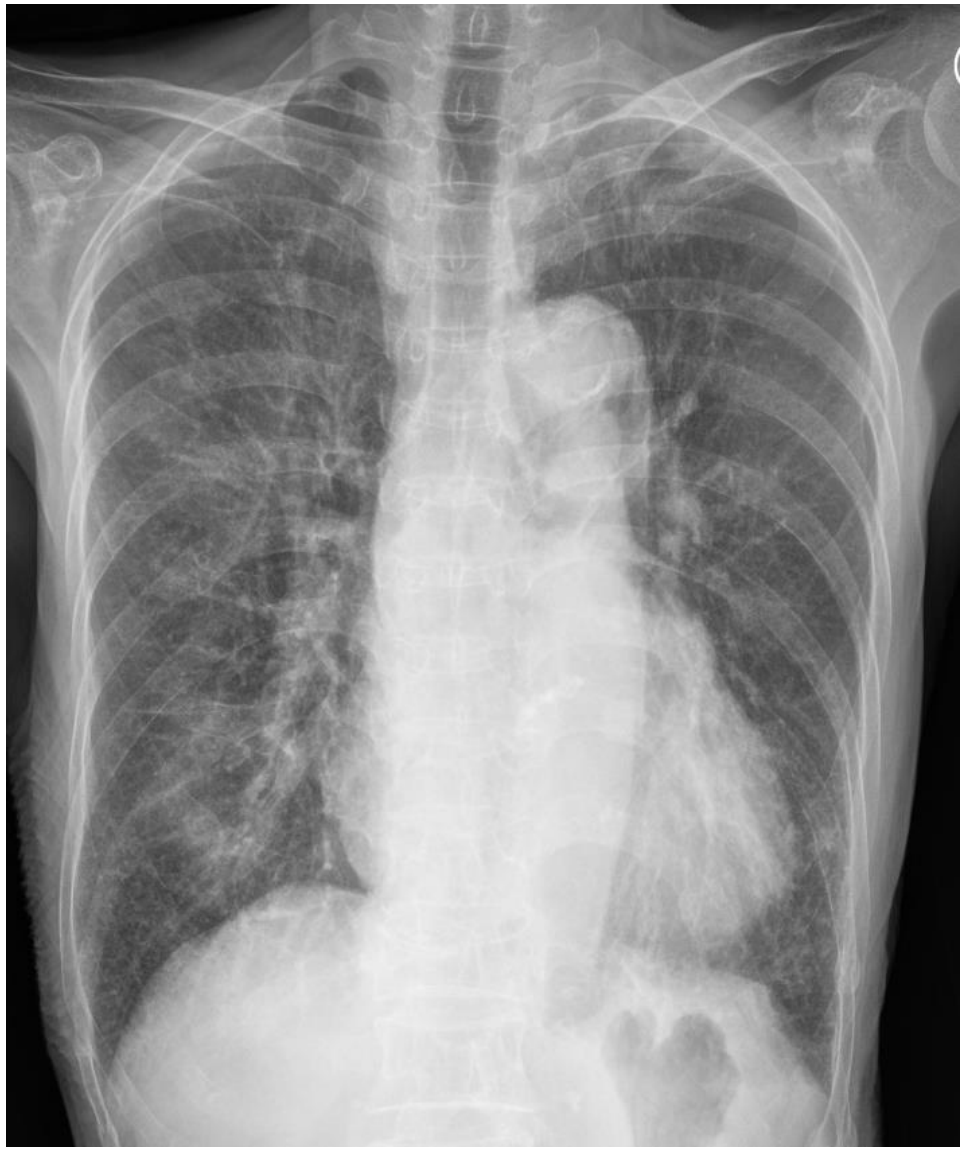
Optimized Feature and benefit for TAVI in Korea

- Conduction disorders
- Hemodynamics
- Paravalvular leak
- Coronary access
- Durability

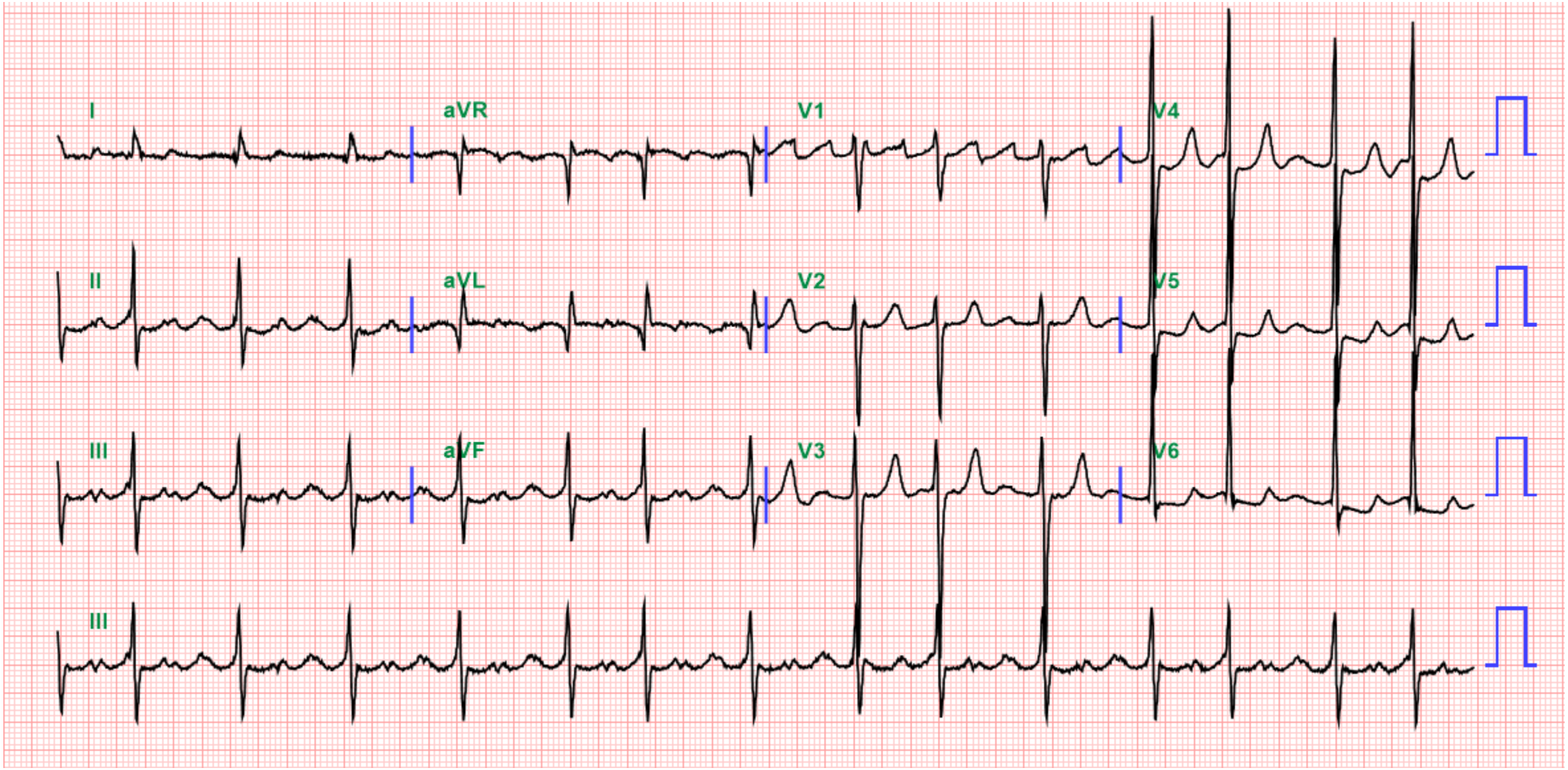
Case 81 years old, female

- Sx: aggravated DOE
- PHx:
  - HTN
  - CAD, S/P PCI at LAD
  - COPD

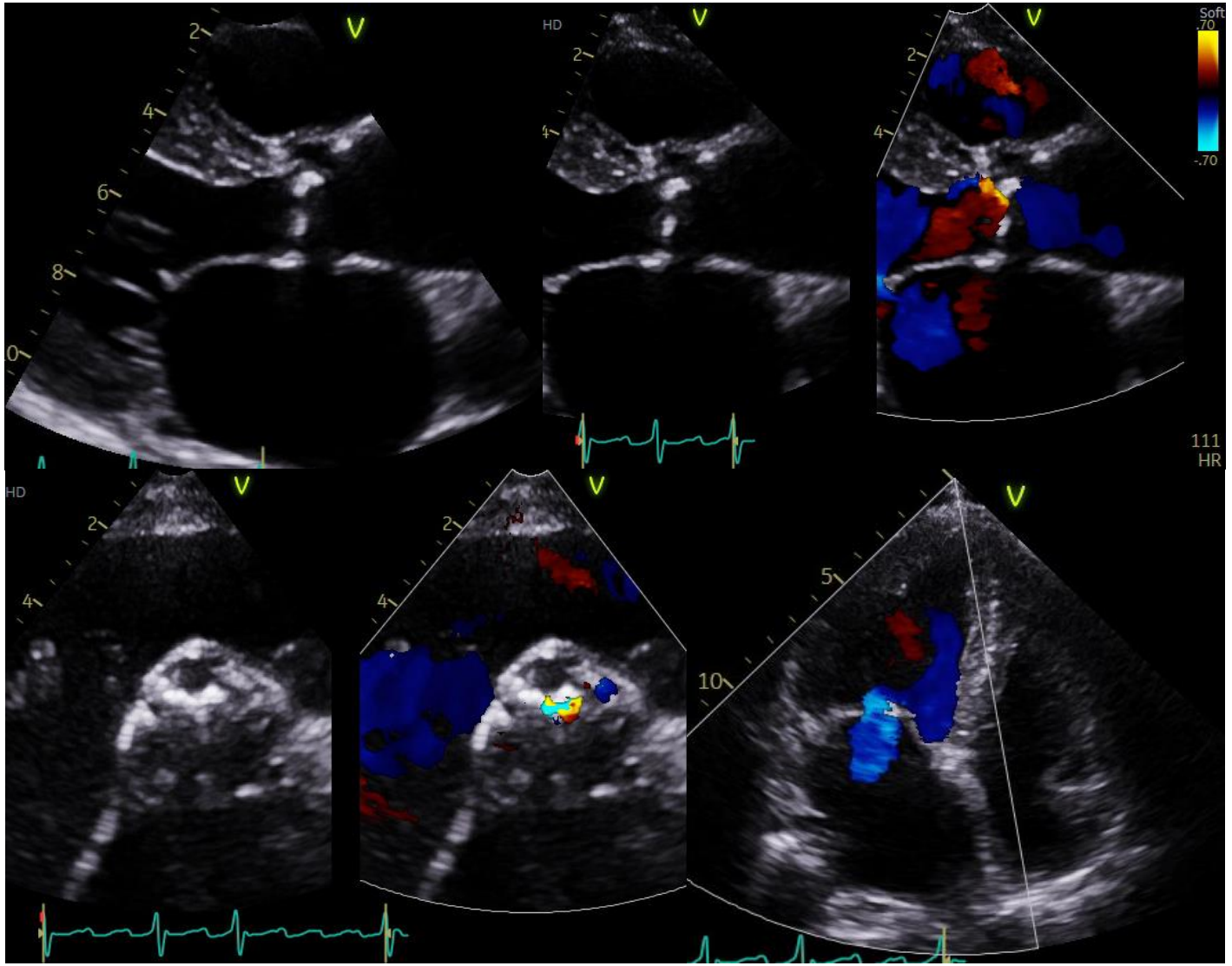
- Body Ht/Wt:
- Lab: Cr 0.7 mg/dL
  eGFR 79 ml/min/1.73
- STS: 8.36%



Baseline ECG



Baseline TTE



Severe AS with mild AR

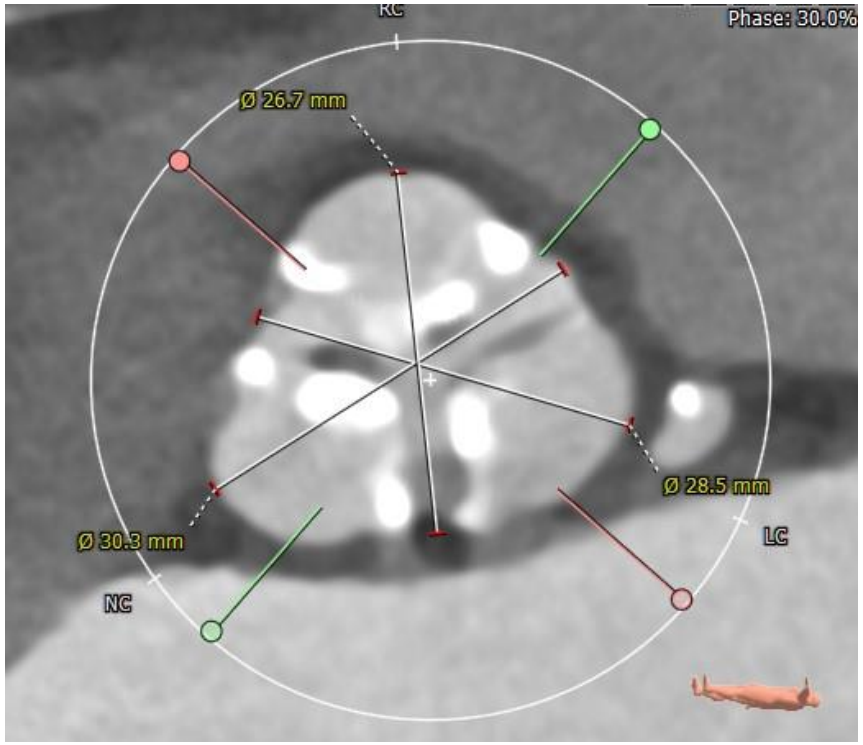
AVA 0.38cm2

PSPG/MSPG 95/66mmHg

LVEF=46%

CT Analysis

Annulus Area
(Perimeter derived : 23.6mm)

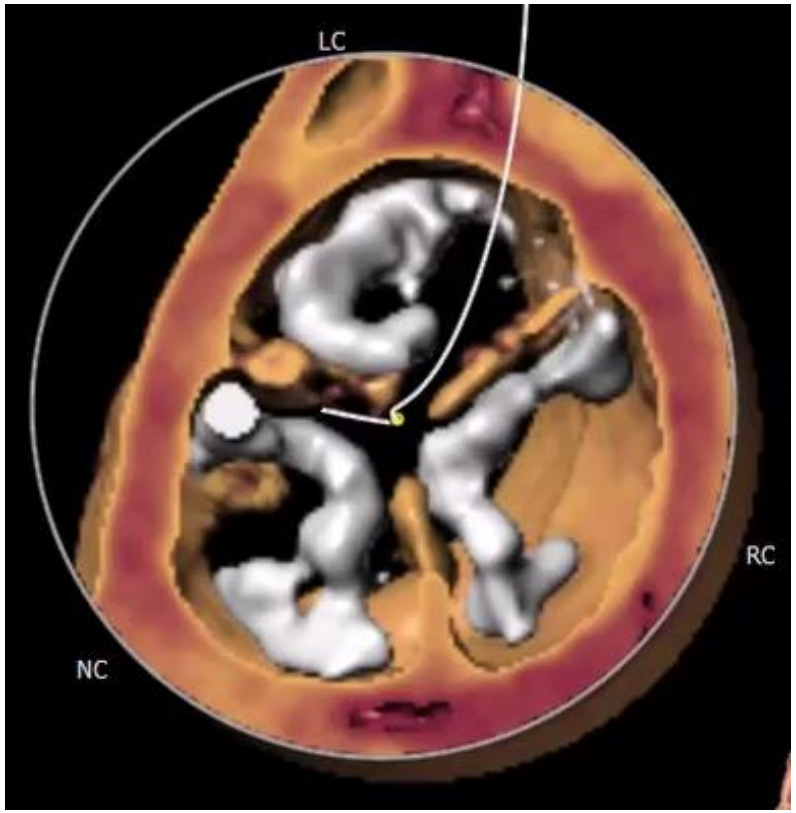


<SOV>

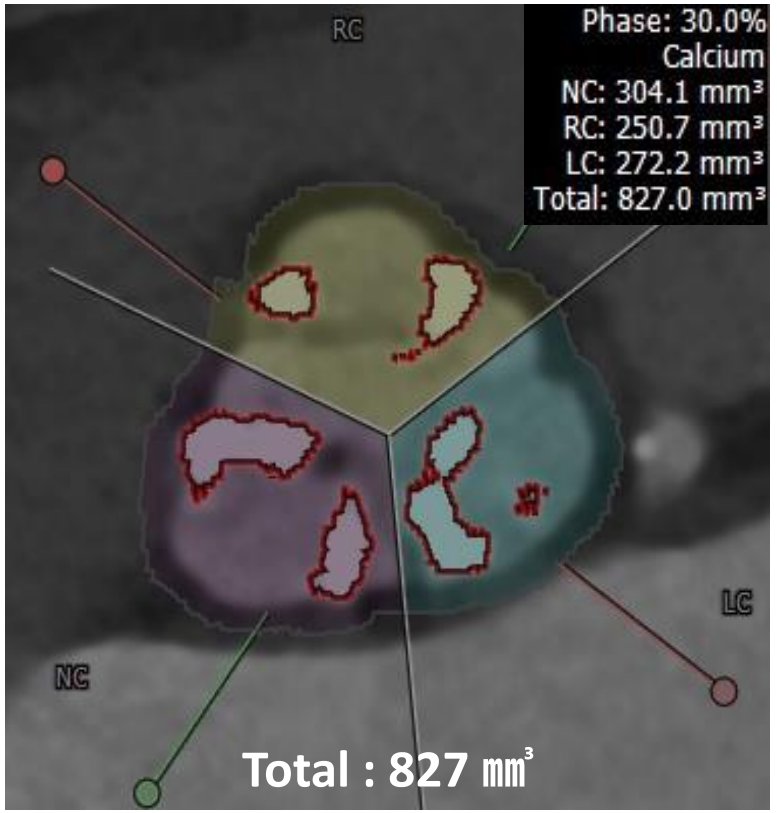
<Lt Coronary Height>

CT Analysis

Annulus Calcification



Annulus Calcification (VR)



Calcium Score (HU 750)

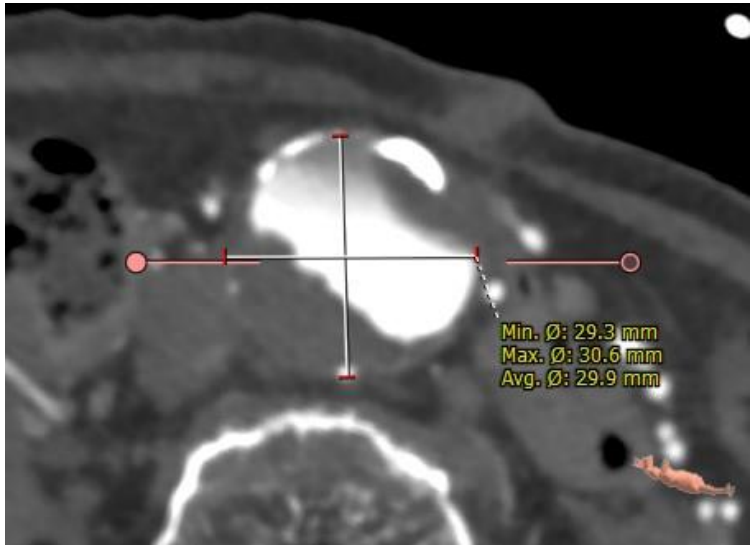
CT Analysis

Valve Sizing

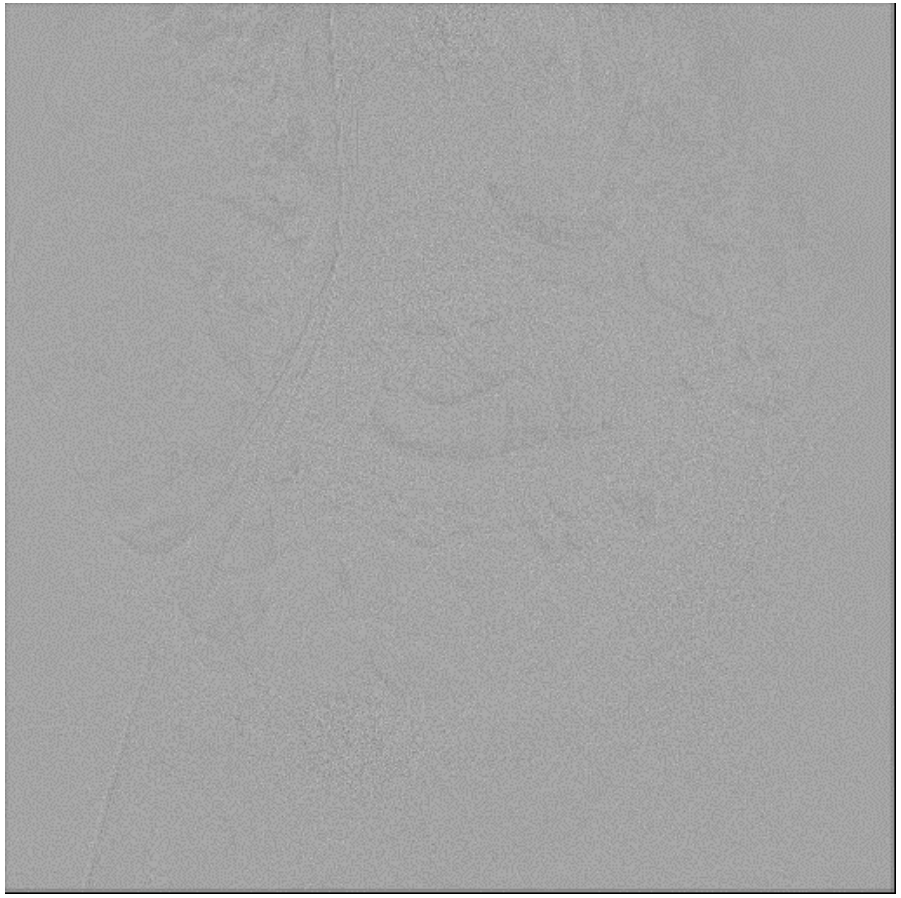
13.9% oversizing

S – 23 mm | **M – 25 mm** | **L – 27 mm**

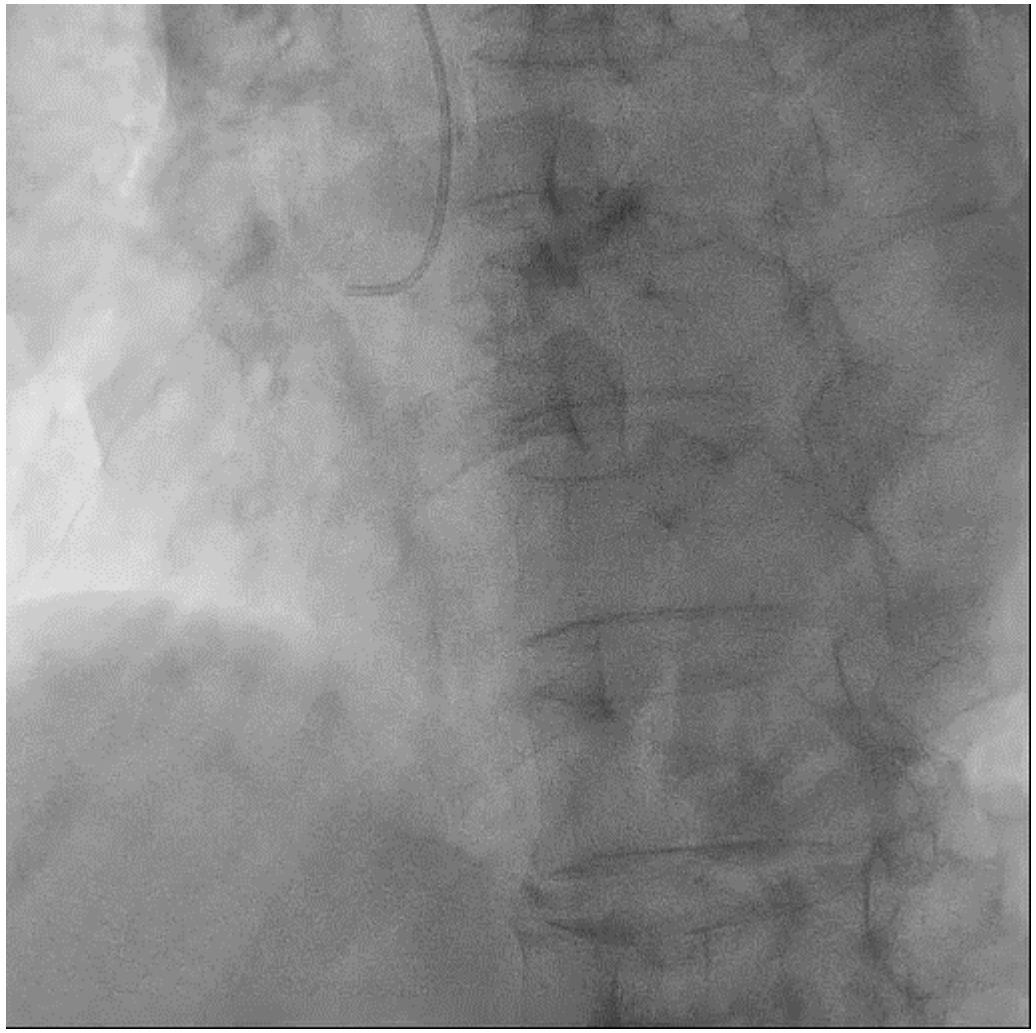
ACURATE neo2™ Aortic Valve			
Aortic annulus diameter*	21 mm ≤ annulus diameter ≤ 23 mm	23 mm < annulus diameter ≤ 25 mm	25 mm < annulus diameter ≤ 27 mm
Aortic annulus perimeter (mm)	66 mm ≤ annulus perimeter ≤ 72 mm	72 mm < annulus perimeter ≤ 79 mm	79 mm < annulus perimeter ≤ 85 mm

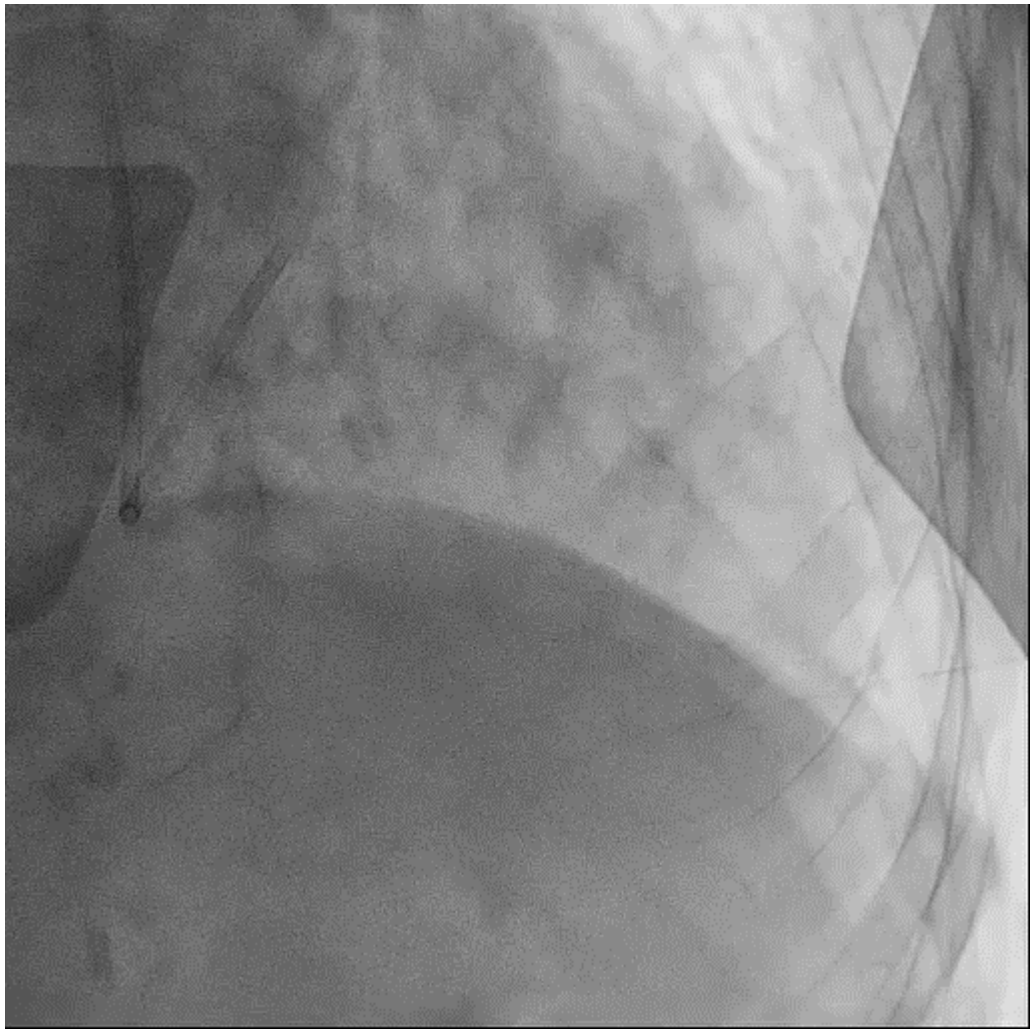


AAA (30mm)



Coronary angiography

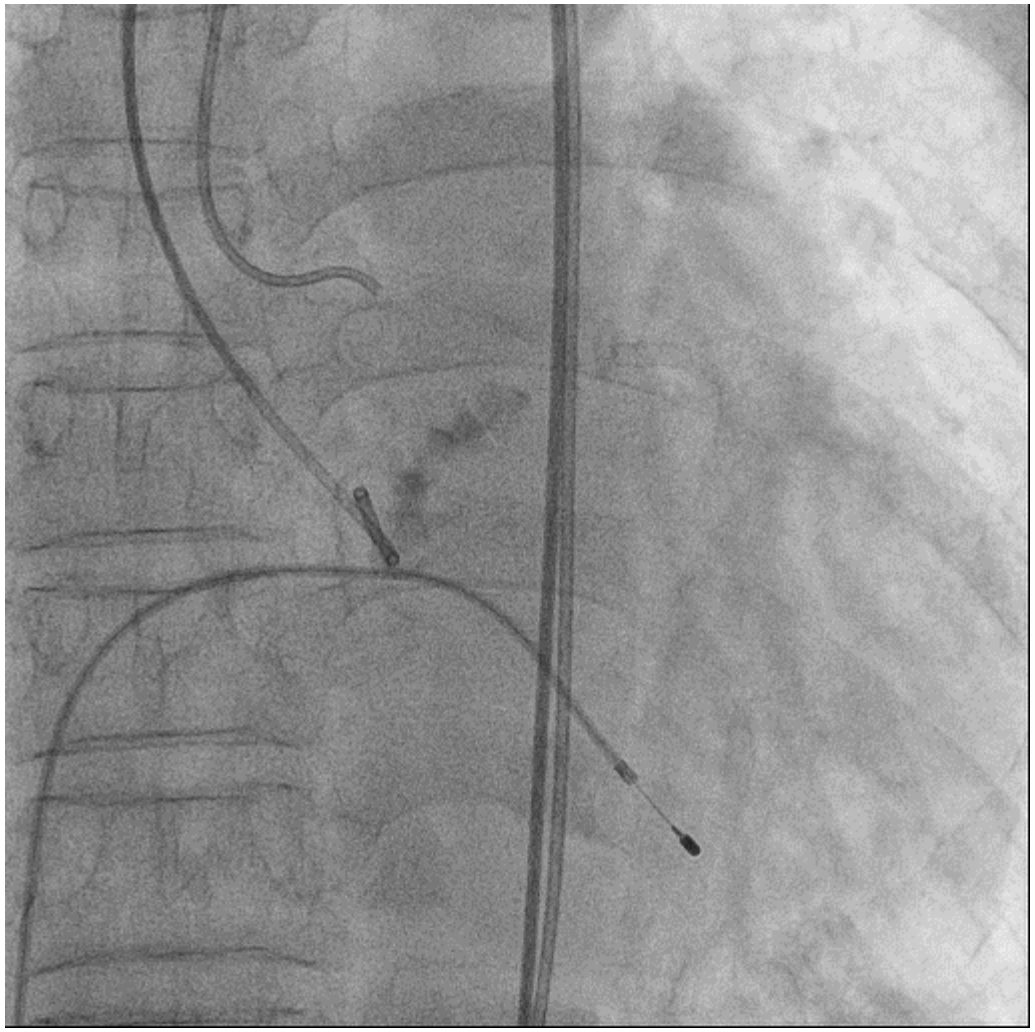




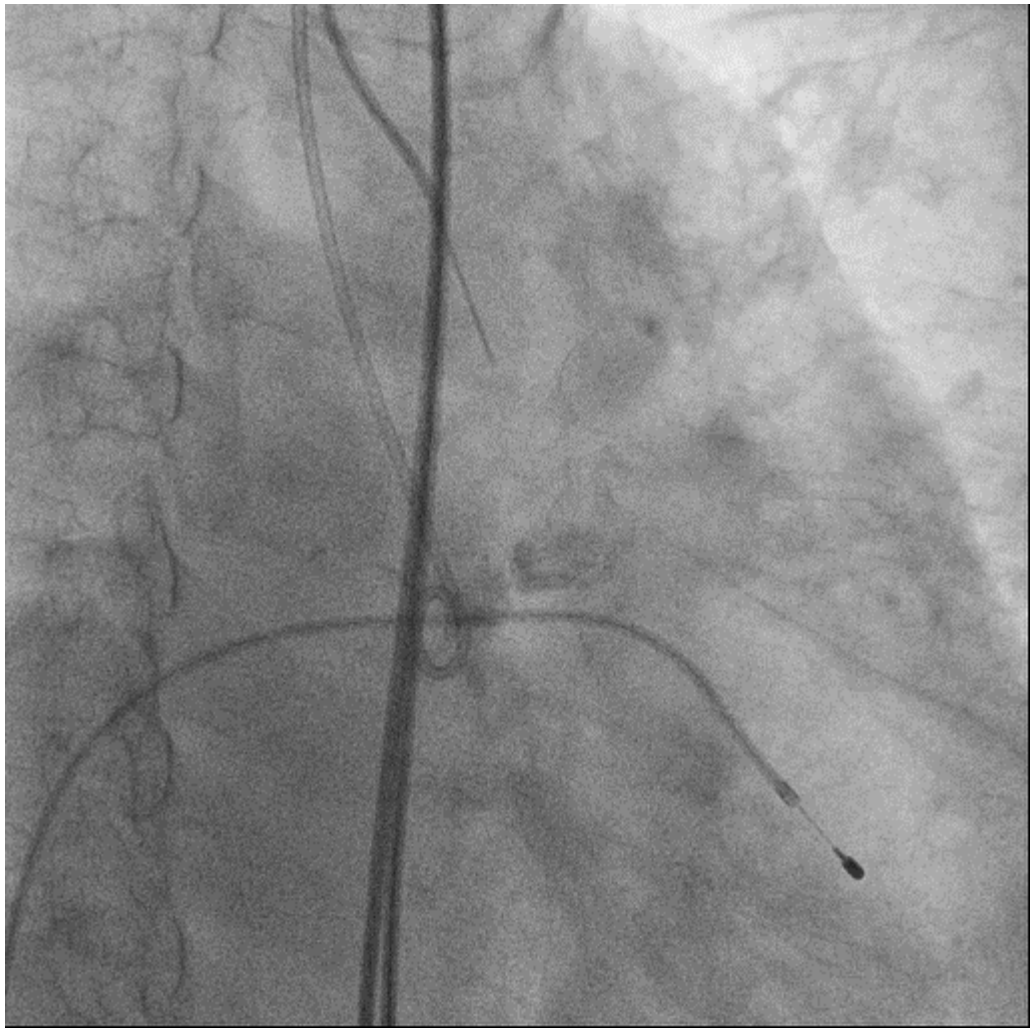
Patent prev mLAD stent

Case Summary

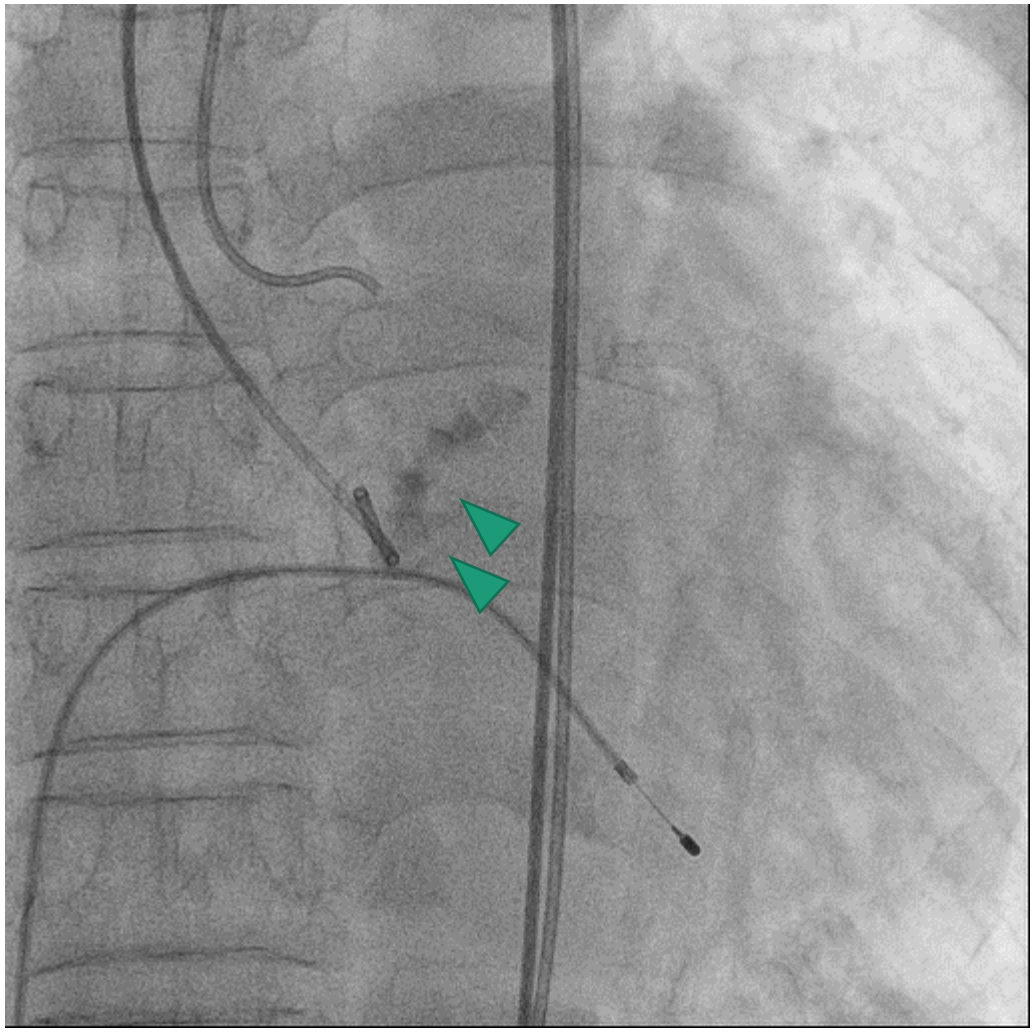
- Elderly Korean female patient
- Very small body stature
- Small annulus & SOV
- Annulus Calcification
- Known CAD s/p PCI
- Atrial flutter



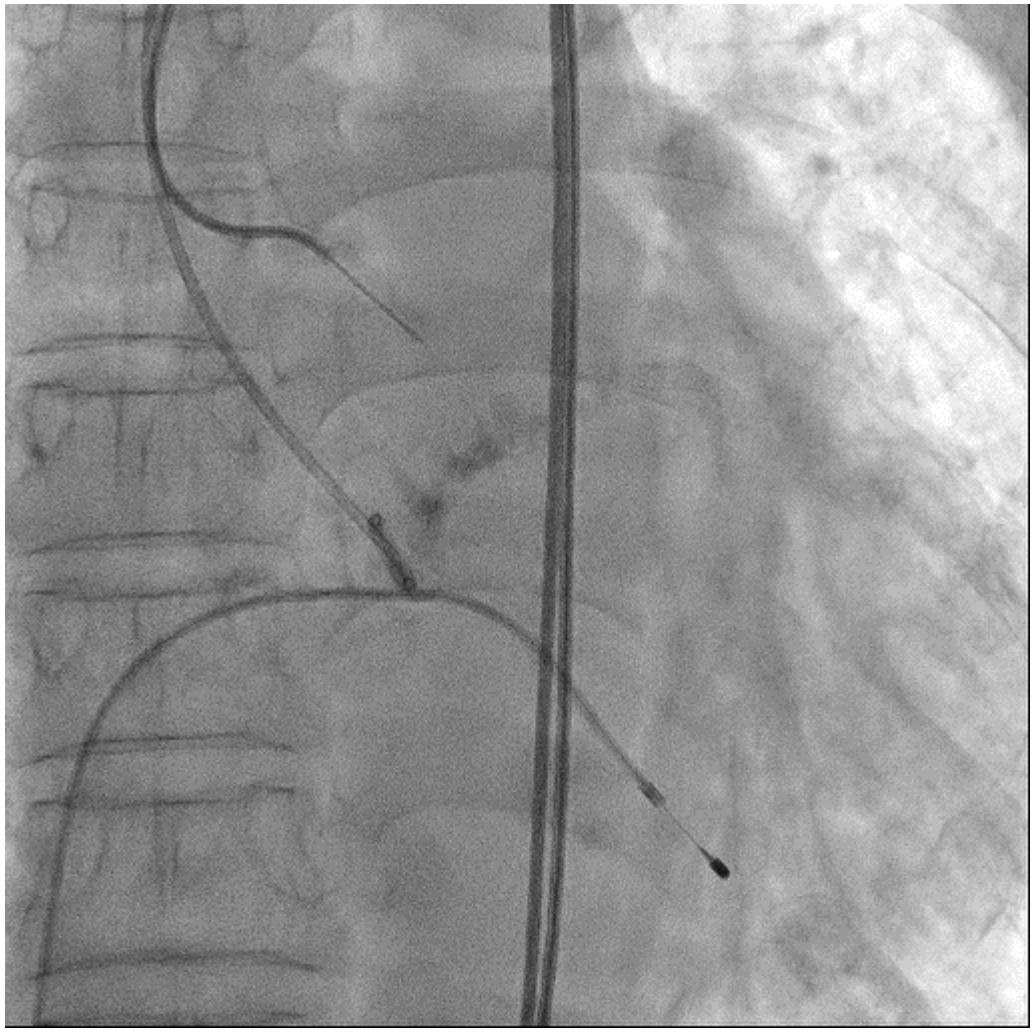
3-Cusp View



Cusp Overlap View



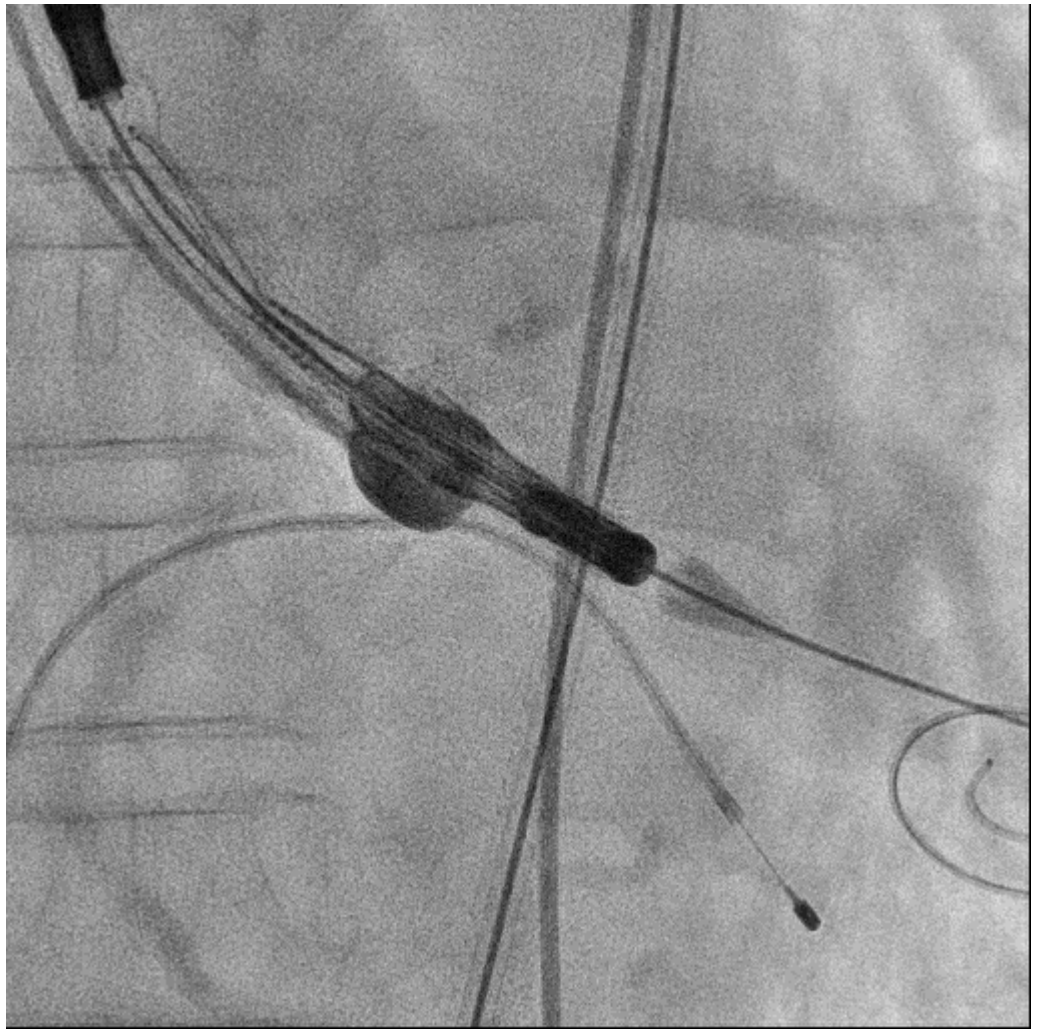
3-Cusp View



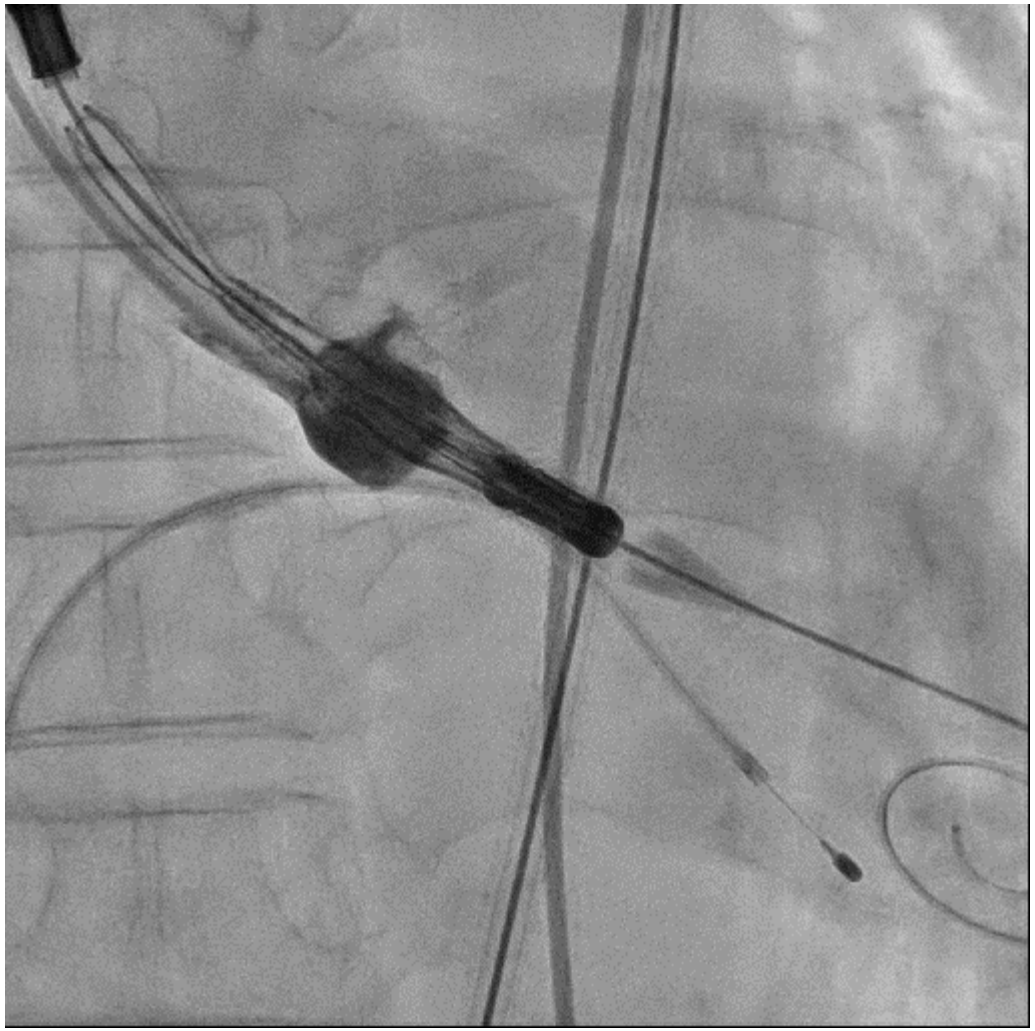
Wire Crossing

Pre Balloon

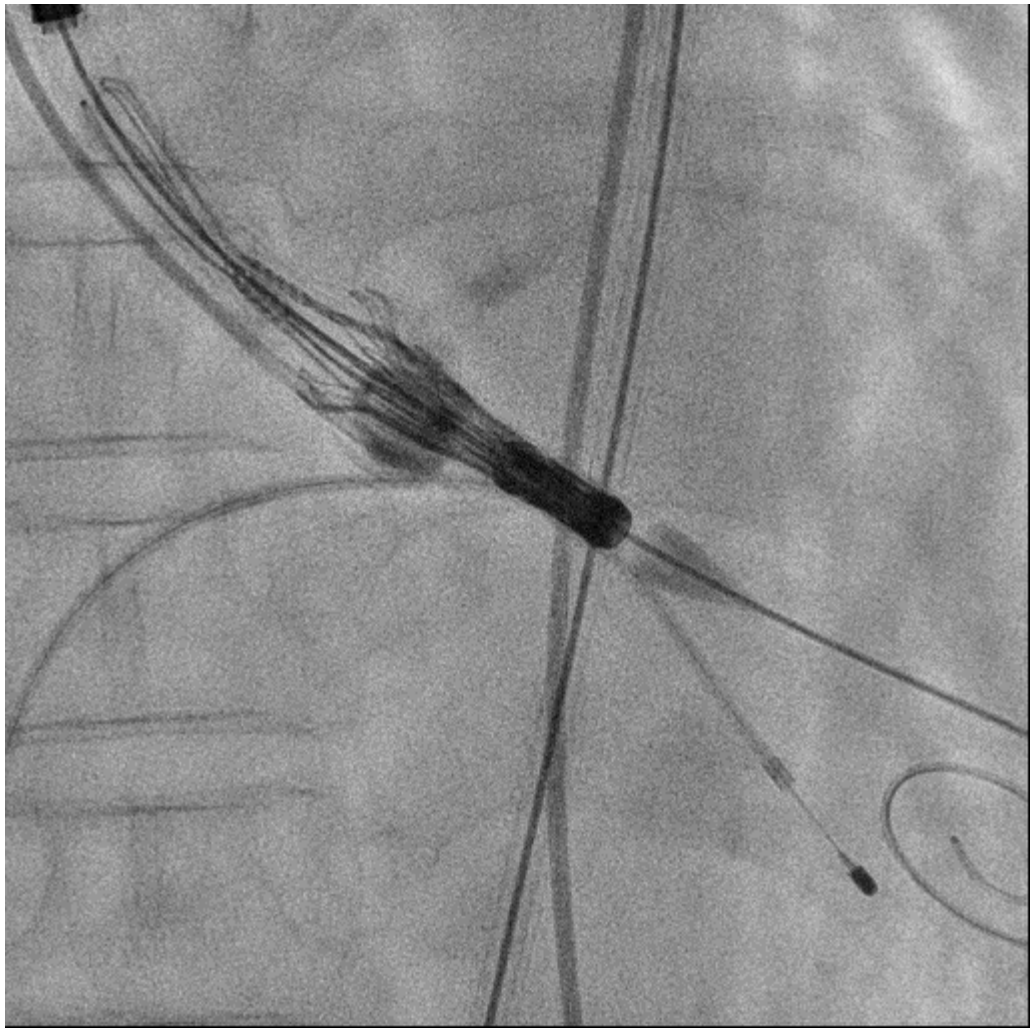
Z-med 22mm x 40mm



Position Confirm

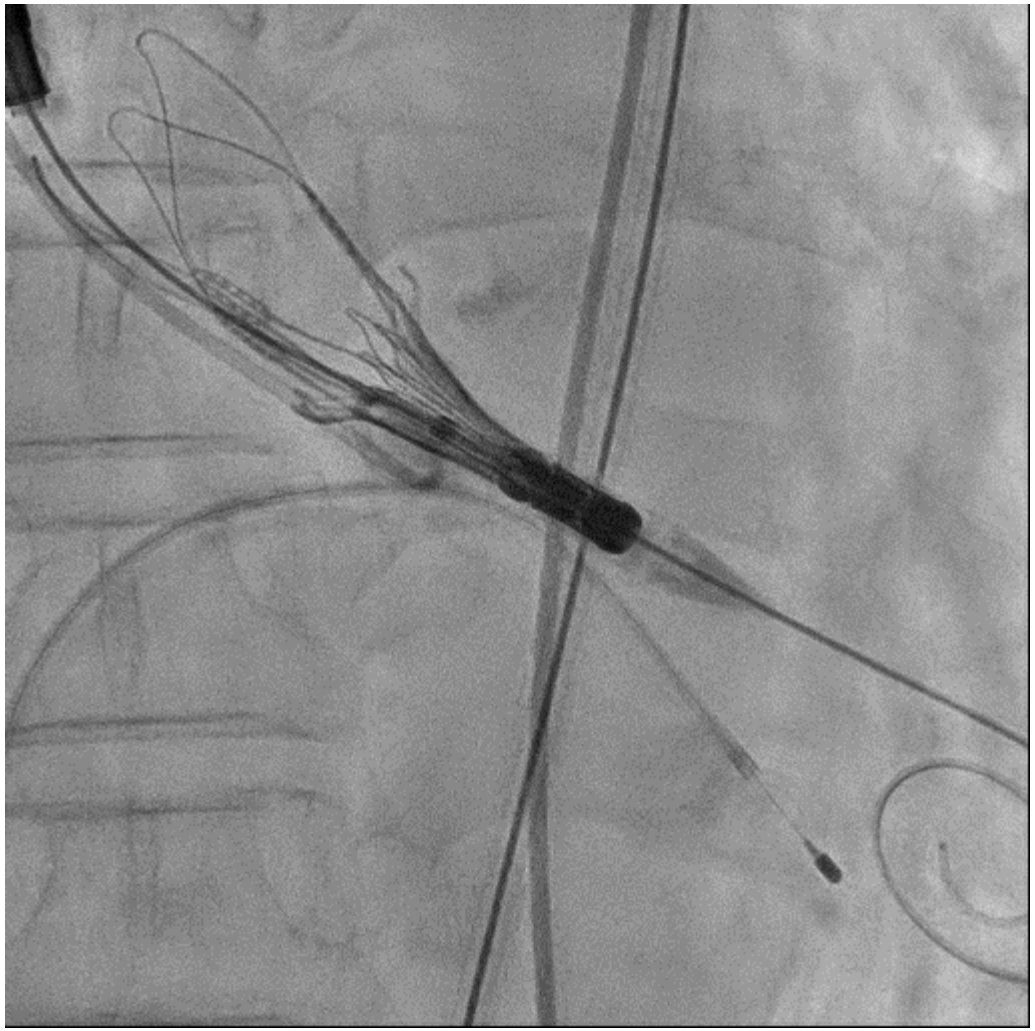


Upper Crown

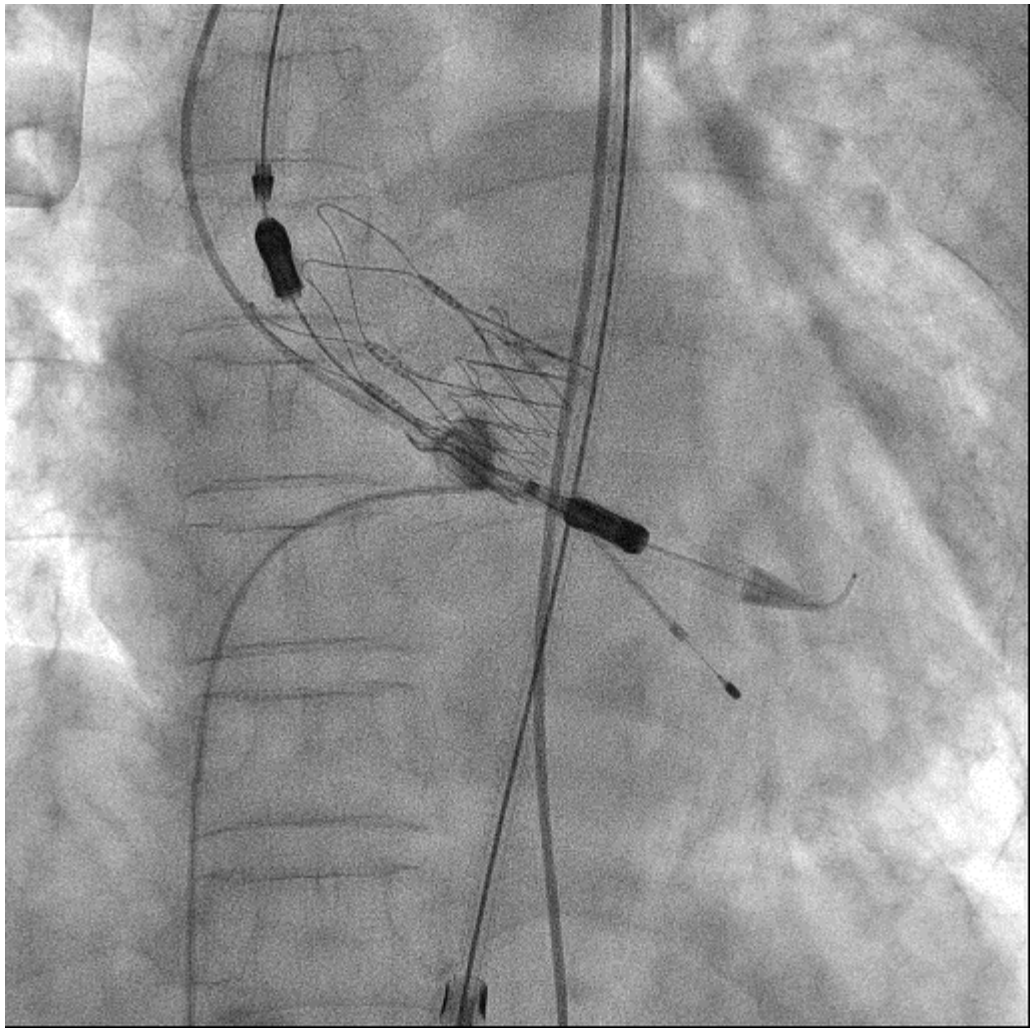


Stabilization Arches

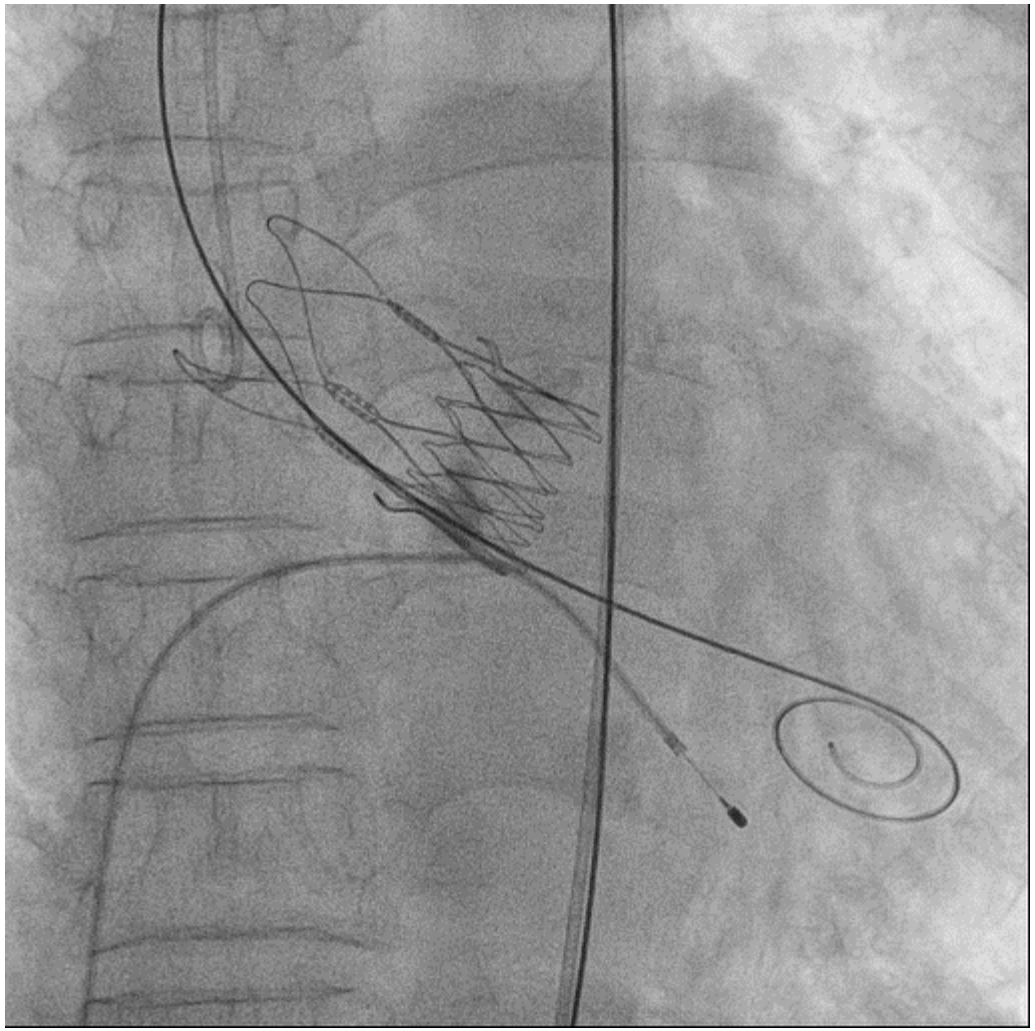
Have push force on delivery system !!



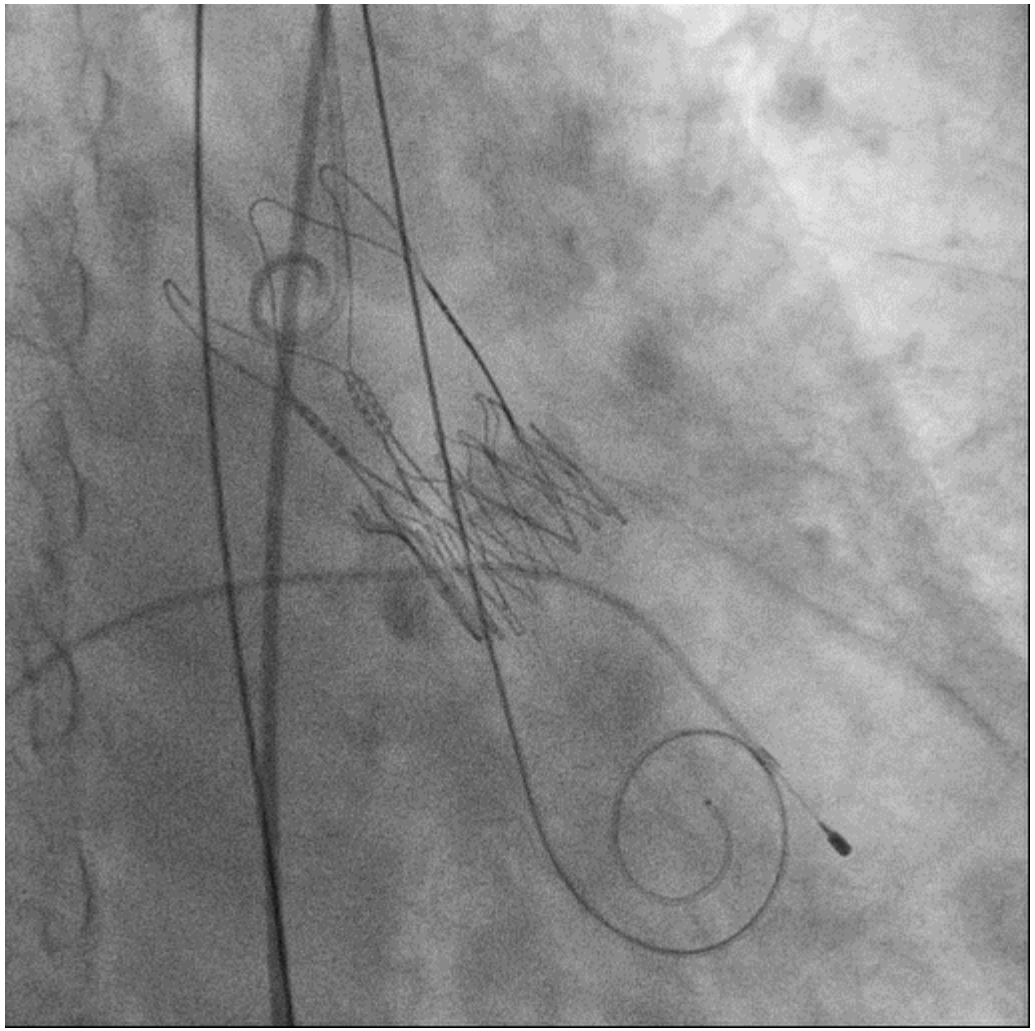
Acurate Neo2 25mm(M size) Valve Deploy
with Control Pacing 150bpm



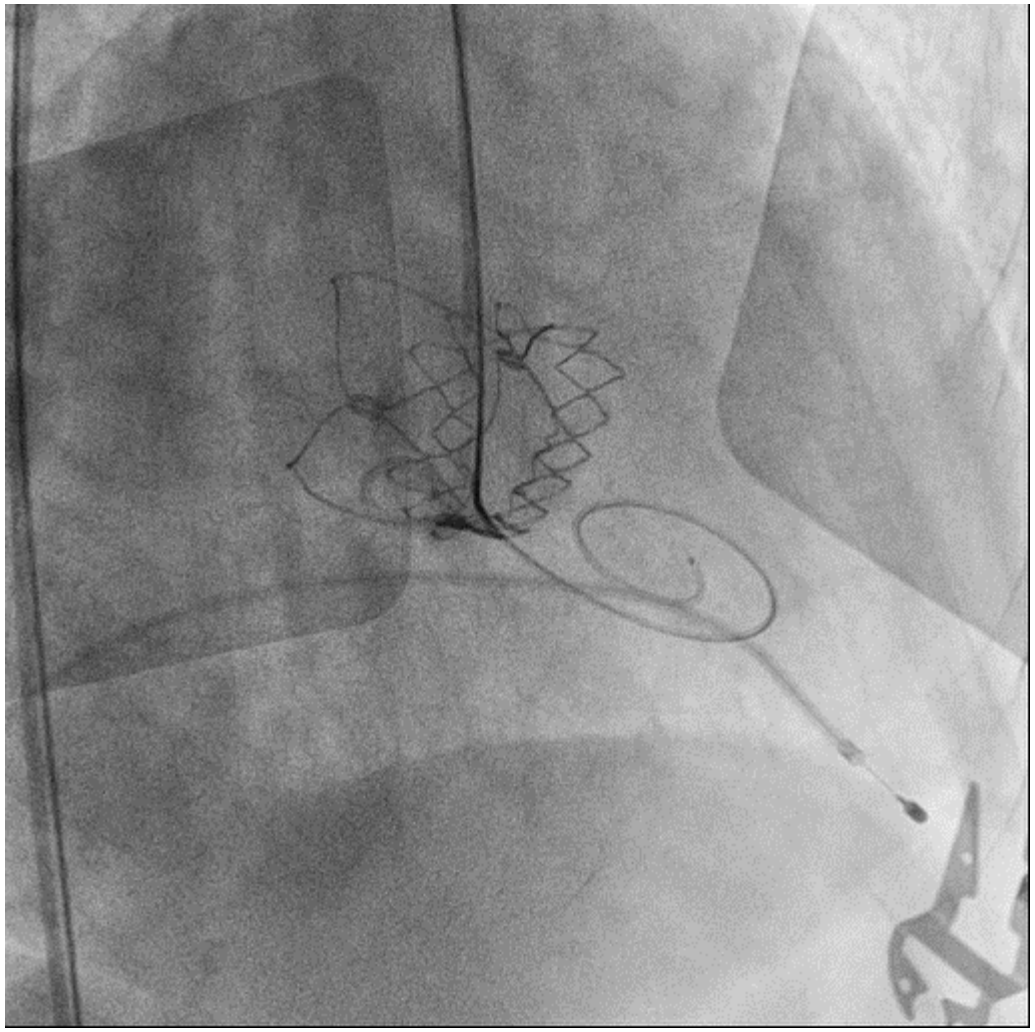
Delivery System Remove
(Safari Wire Pull)



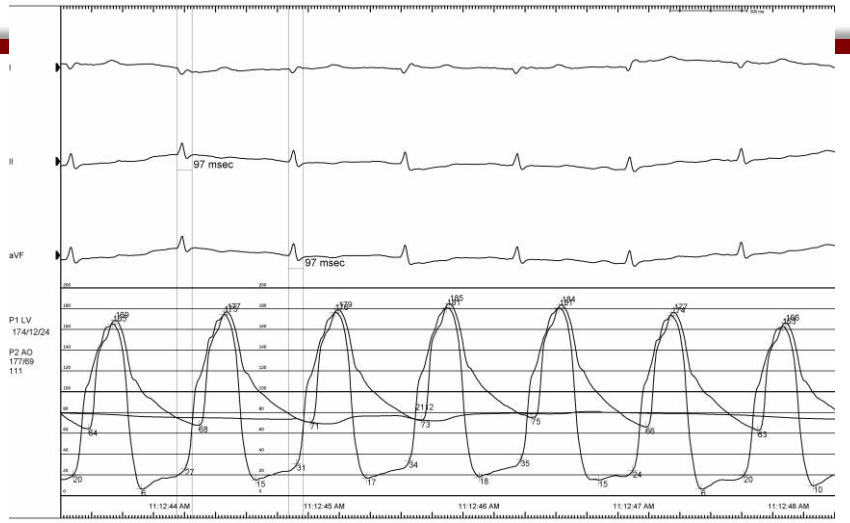
3 Cusp Angle (LAO 3 CAU 10)



Cusp Overlap Angle (RAO 21 CAU 41)



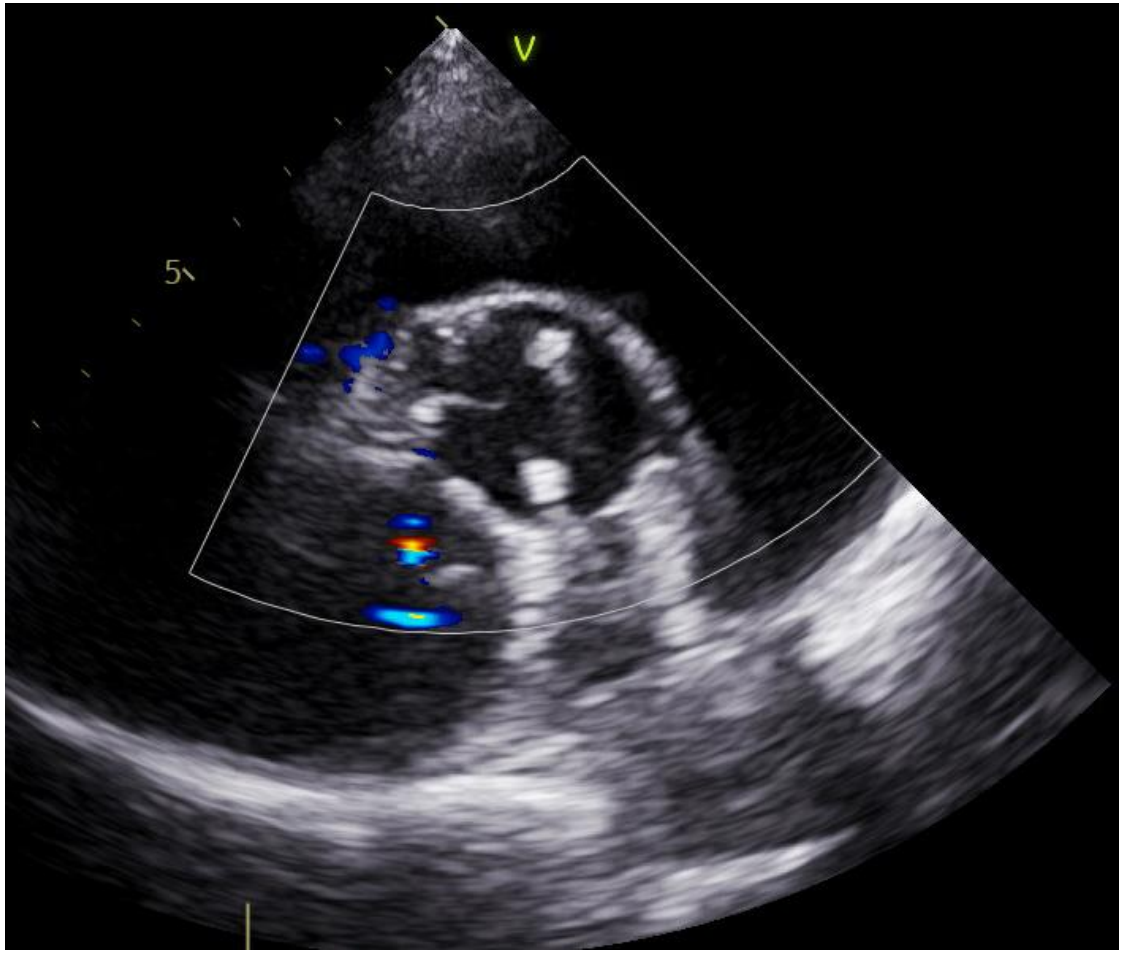
RAO 45 Cranial 30 (Oval Shape)

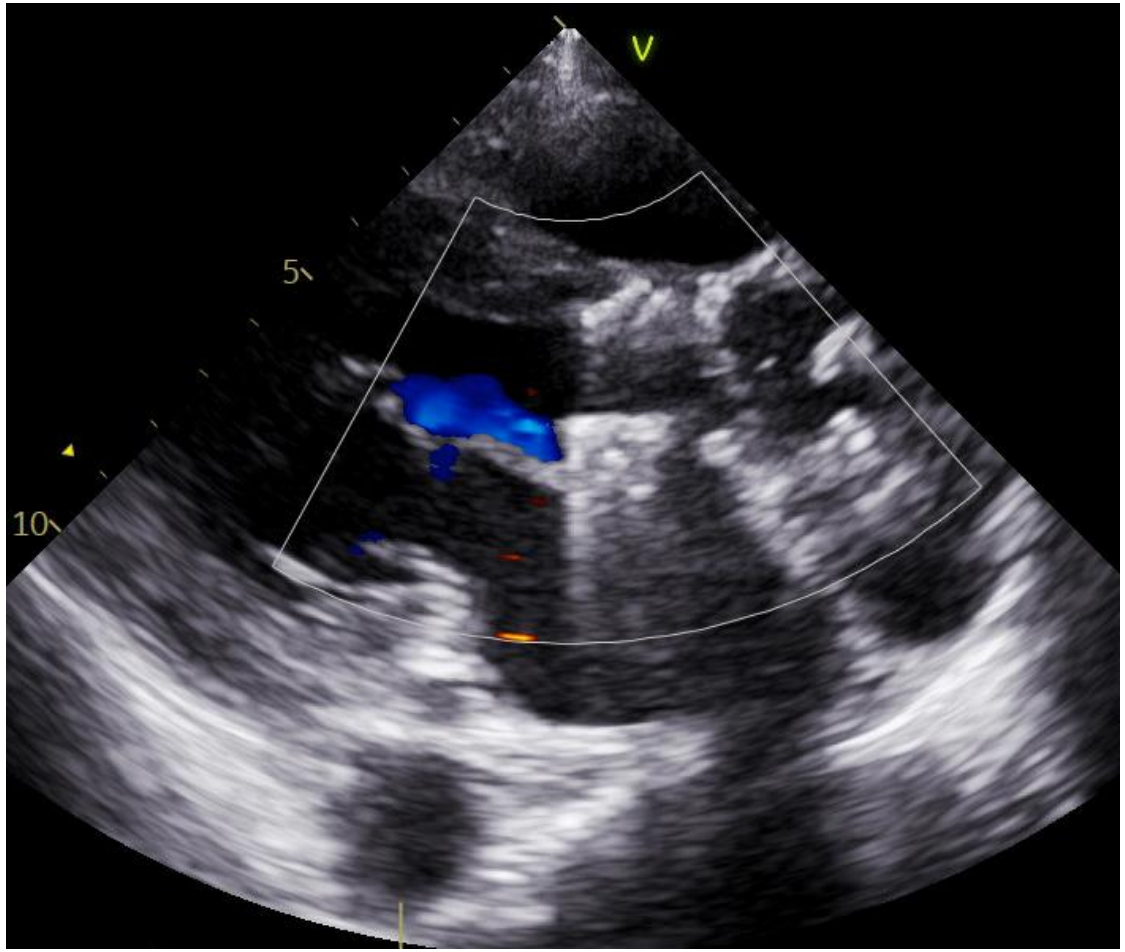


AR index			
DPB(Ao)	**LVEDP**(LV)	**SBP**(Ao)	AR index
69	28	177	23.163842

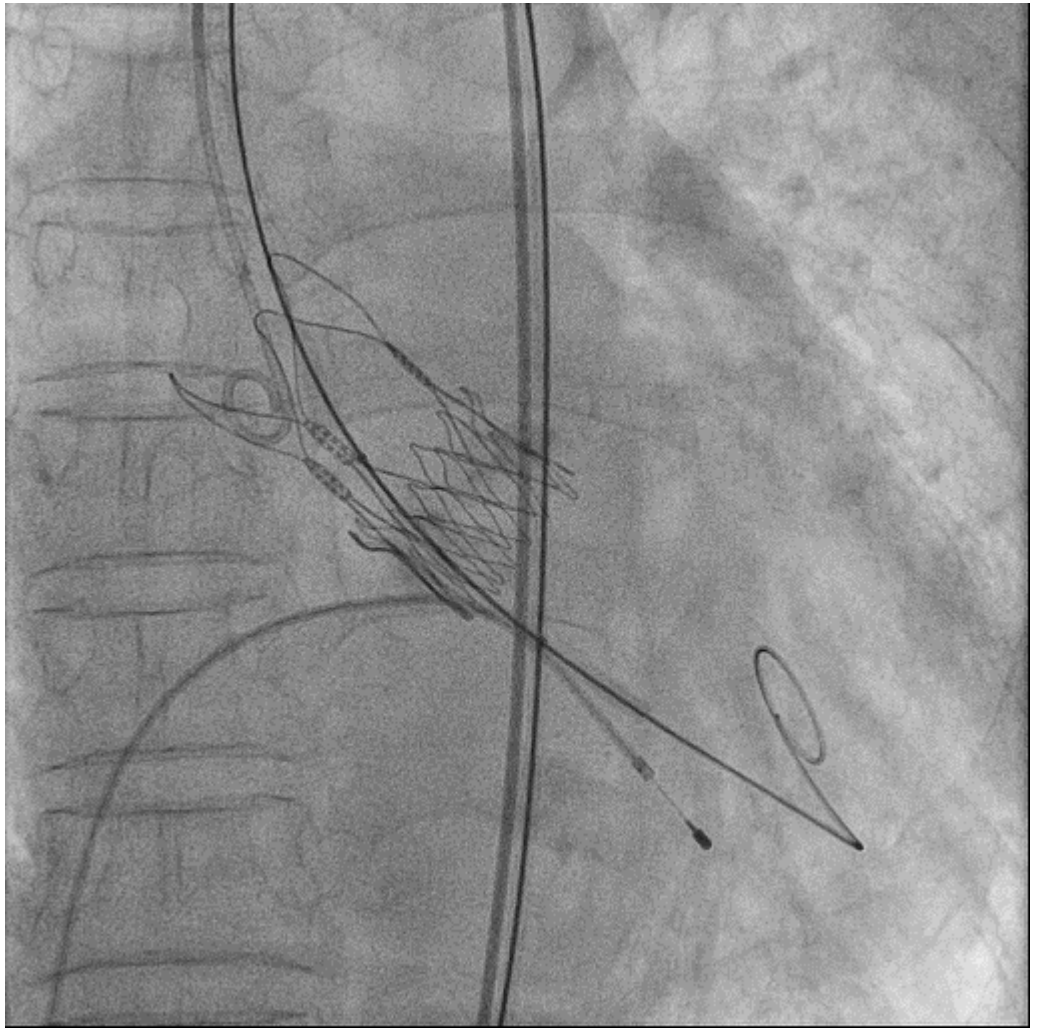
PVL AR Grade	AR Index	Rough Value
None	31.7 ± 10.4	40s
Mild	28.0 ± 8.5	30s
Moderate	19.6 ± 7.6	20s
Severe	7.6 ± 2.6	10s

TAVI echo after deployment



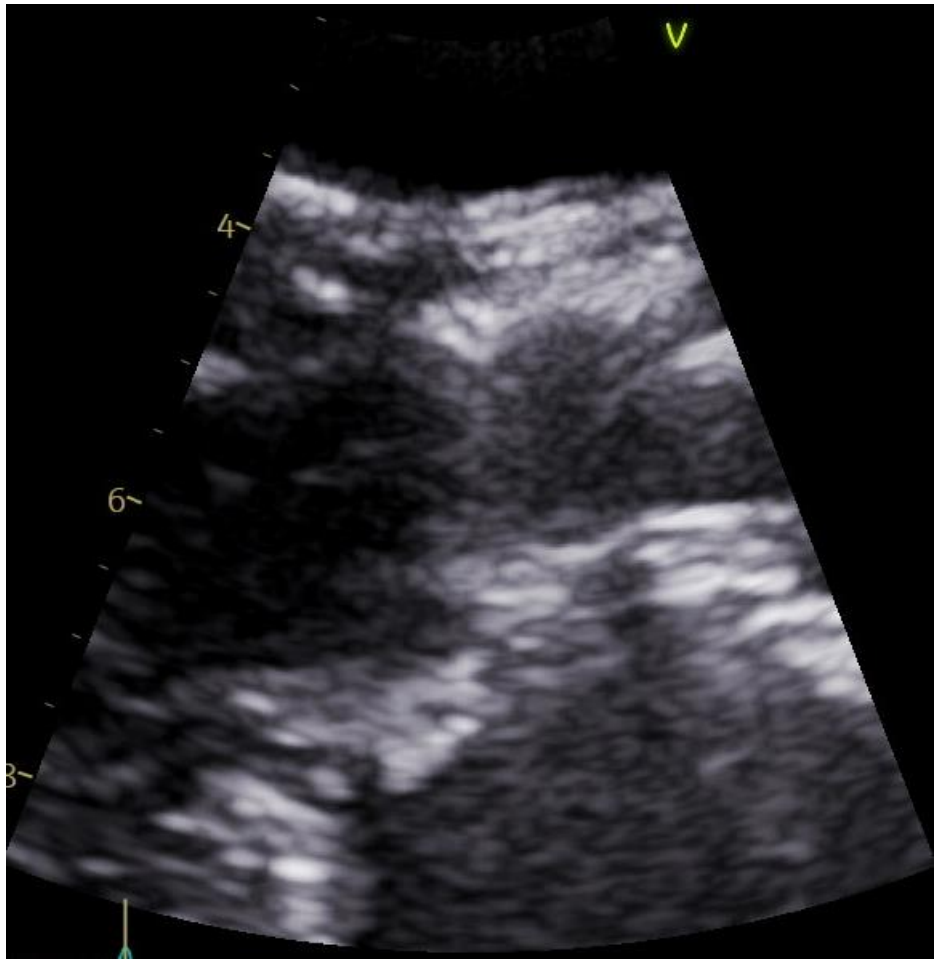


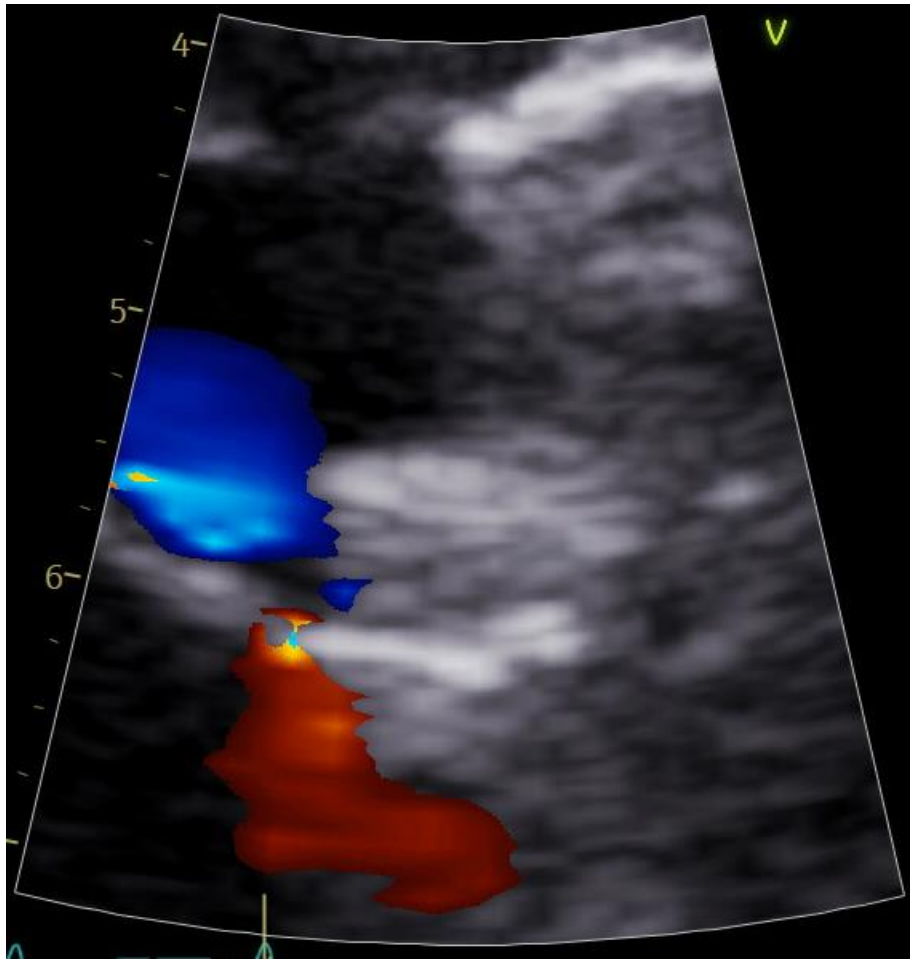
Post balloon

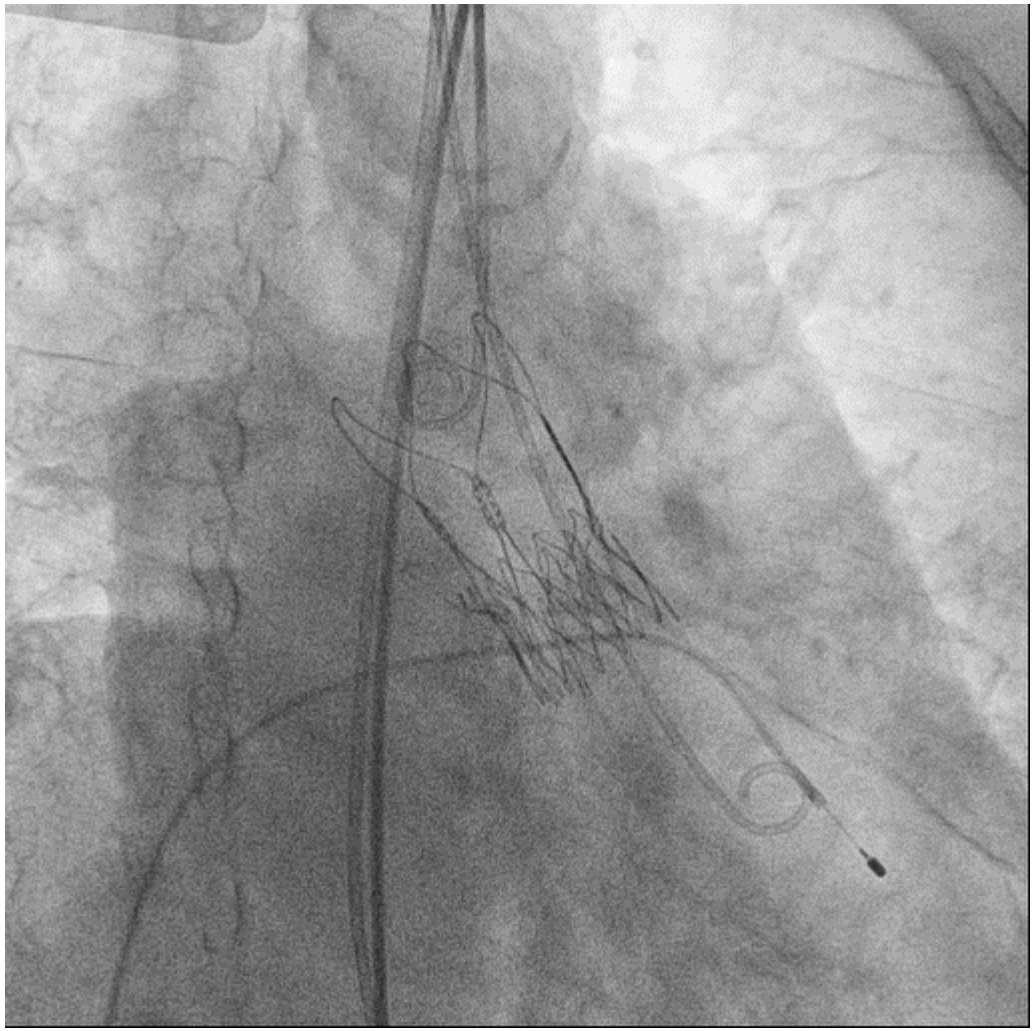


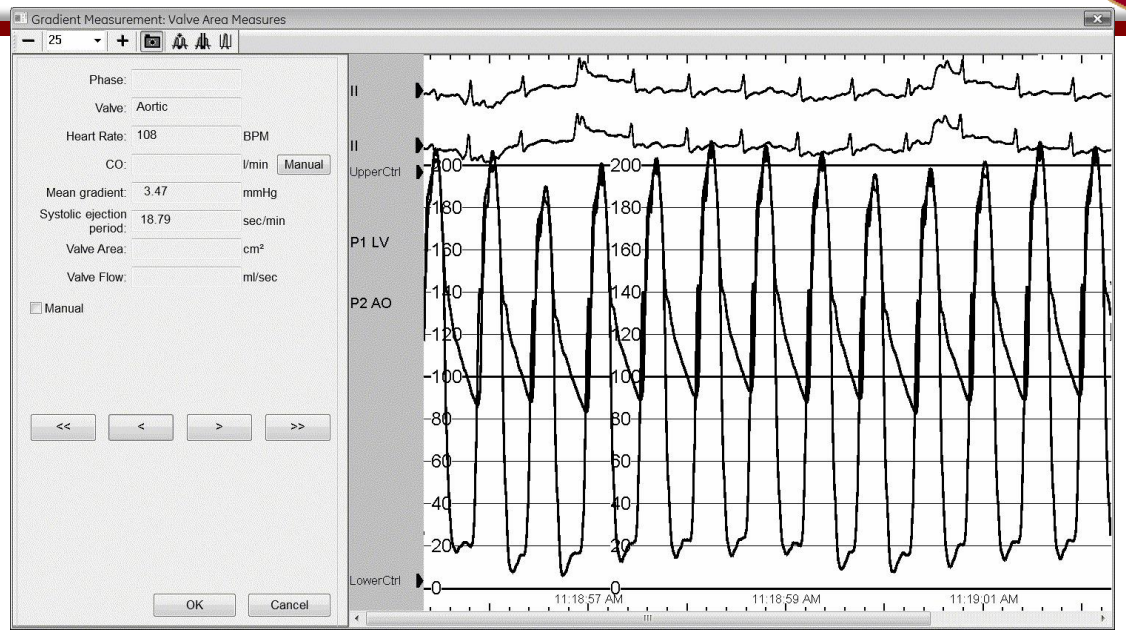
Post Dilatation Z-med 23mm

TTE after post ballooning







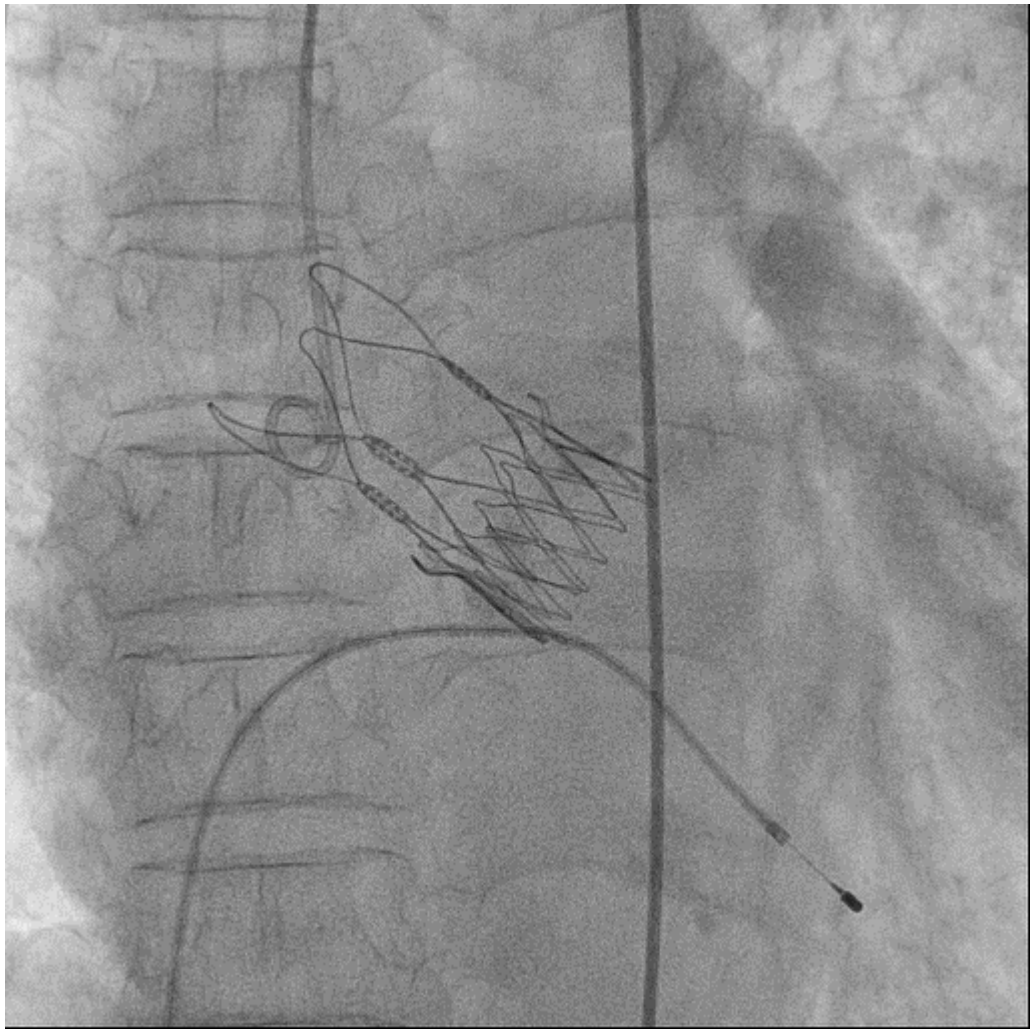


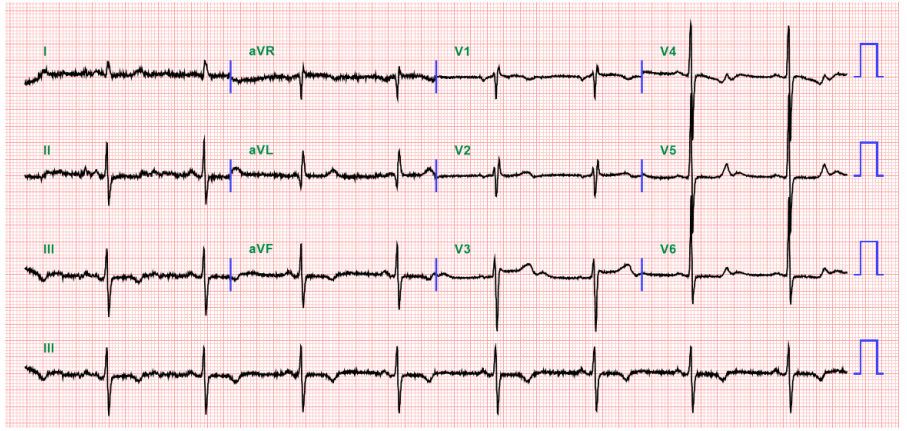
AR index			
DPB(Ao)	**LVEDP**(LV)	**SBP**(Ao)	AR index
89	20	204	33.823529

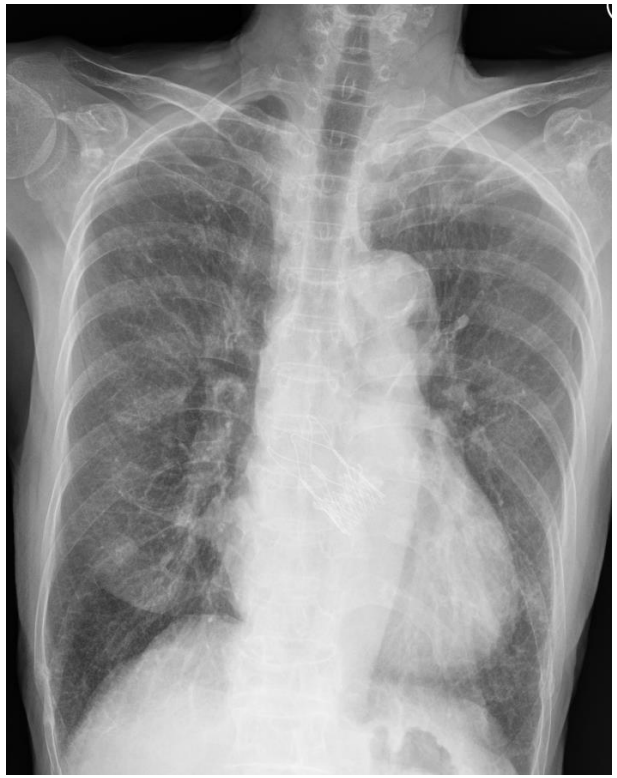
PVL AR Grade	AR Index	Rough Value
None	31.7 ± 10.4	40s
Mild	28.0 ± 8.5	30s
Moderate	19.6 ± 7.6	20s
Severe	7.6 ± 2.6	10s

Pressure Gradient & AR Index

Final







ACURATE neo2 in KUMC Anam (n=18)

Age	85 yrs
BMI	24.1 kg/m^2
Female	66.7%
Size	
23(S)	27.8%
25(M)	50.0%
27(L)	22.2%
Annulus	23.2
STJ	28.8

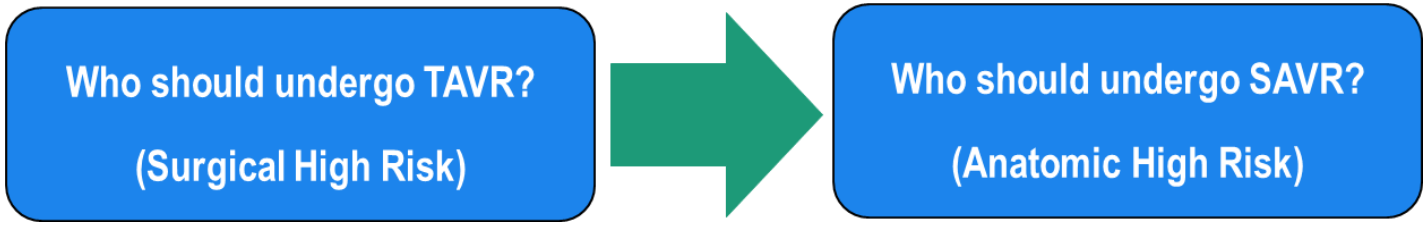
Case patient

Elderly Korean Female patient
Very small body stature
Small annulus & SOV

Annulus Calcification
Known CAD s/p PCI
Atrial flutter

Conclusion

- The indications for TAVI is expanding.



- Optimized Feature and benefit of TAVI is expanding.
  - Mortality
  - Quality of life
  - Conduction disorders
  - Durability
  - Hemodynamics
  - Paravalvular leak
  - Coronary access

- **ACURATE neo2 will provide optimized feature and benefit of TAVI in Korea.**